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design and protocol for a comprehensive evaluation of a massive open online course (MOOC) on quality improvement in healthcare

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Title: Study design and protocol for a comprehensive evaluation of a massive open online course (MOOC) on quality improvement in healthcare

Running title: Quality Improvement MOOC

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ABSTRACT

Introduction Massive Open Online Courses (MOOCs) offer a flexible approach to online and distance learning, and are growing in popularity. Several MOOCs are now available, to help learners build on their knowledge and skills in a number of healthcare topics. More research is needed to determine the effectiveness of MOOCs as an online education tool, and explore their longer-term impact on learners' professional practice. We present a protocol describing the design of a mixed-methods evaluation of a MOOC designed to strengthen learners' knowledge and confidence with engaging in quality improvement (QI) activities, as well as to signpost resources and additional learning and training opportunities.

Methods and analysis A pre-post study design using quantitative and qualitative methods will be used to evaluate the QI MOOC. Different elements of the RE-AIM (reach, effectiveness, adoption, implementation, and maintenance) and Kirkpatrick models will be used to guide the evaluation. All learners who register for the course will be invited to participate in the QI MOOC evaluation study. Those who consent will be asked to complete a pre-survey to assess baseline QI knowledge (self-report and objective) and perceived confidence in engaging in QI activities. Upon completion of the course, participants will complete a post-survey measuring again knowledge and perceived confidence. Feedback on the course content and how it can be improved will be obtained. A sub-set of participants will be invited to take part in a follow-up qualitative interview, three months after taking the course, to explore in-depth how the MOOC impacted their behaviour in practice.

Ethics and dissemination: The study has been approved by the University of Bath Human Research Ethics Committee (reference: 2958). Study findings will be published in peer-reviewed journals, and disseminated at conference and departmental presentations, and more widely using social media, microblogging sites and periodicals aimed at healthcare professionals.

Strengths and limitations of this study

- Application of the RE-AIM and Kirkpatrick models to capture the impact of the first UK-based QI MOOC on participants' future engagement with QI projects.
- Use of mixed methods to conduct a comprehensive evaluation of the QI MOOC and contribute to evidence on MOOC effectiveness in healthcare settings.
- Limited control over participant study recruitment and retention given all learners who register for the MOOC will be invited to take part in the study.

Keywords: MOOC, Massive Open Online Course, quality improvement, healthcare, evaluation, Kirkpatrick model, RE-AIM

Word limit: 3,282 words (excluding tables, abstract and references)

INTRODUCTION

In an era of online education and distance learning, Massive Open Online Courses (MOOCs) provide a platform to disseminate information on a large-scale and reach a global audience with different disciplinary and cultural backgrounds [1]. MOOCs are generally offered for free, and developed by academics working in higher education institutes, in collaboration with professional and commercial organisations who host the MOOCs via their online platforms [2]. They have predominately been created in developed countries such as Australia, the United States, and the United Kingdom, although their potential in developing countries is increasingly recognised [3 4]. Most MOOCs use a variety of learning formats such as video lectures, online discussion, articles, recommended reading lists and self-assessments/ quizzes, to engage learners within a global virtual classroom setting [5 6].

Despite MOOCs growing in popularity over the past decade, more research is needed to better understand the role and impact of MOOCs as an online learning tool compared to more traditional methods of teaching and learning [7 8]. Evidence is needed on why so many people enrol in MOOCs yet do not fully complete or drop out of the course, or what particular formats and materials appeal to particular learners. In addition, very little is known about the longer-term impact of MOOCs and whether the knowledge and skills gained through MOOCs make a difference on people's work or practice after taking the course [9].

The number of MOOCs delivering healthcare and continuing medical education is steadily increasing [10-12]. For example, MOOCs have been developed to train physiotherapists about how to manage spinal cord injuries [13 14], improve people's understanding of dementia [15], deliver education to medical students about anatomy [16], educate healthcare professionals on antimicrobial stewardship in low and middle-income countries [17], raise awareness of the real world data science methods in medicine [18 19], and teach students skills of interacting with patients using virtual patients [20]. Results from these studies are somewhat mixed, and MOOCs are perceived to complement rather than override conventional teaching methods [17]. One study found that the MOOC did not increase participant's knowledge and confidence any more than working through an online learning module (Hossain et al. 2015). Further, there are conflicting findings about whether learners enjoy participating in online forums and engaging with other learners on the course [14 16].

Clearly, further research is needed to determine whether MOOCs are successful in engaging learners and delivering education effectively to achieve key outcomes. It is also important to explore the longer-term impact that MOOCs might achieve with regard to learners bringing about change in their work environment through the acquisition of new knowledge, skills and confidence.

The current study focuses on the impact of a MOOC course developed to train healthcare professionals about quality improvement (QI) methods in healthcare. Broadly speaking, QI seeks to improve the delivery of healthcare for patients by enhancing their experience of care and safety [21]. QI involves the application of a systematic approach that uses specific techniques or methods to improve quality [22 23]. QI is widely endorsed by professional bodies around the world [24-26] and has become an important part of medical education curriculum [27 28].

Training healthcare professionals in QI using team-based learning has shown to be an effective way to influence knowledge and behaviour (Armstrong et al. 2012: Jones et al. 2015). For example, a project-based training programme to mentor and support learners in designing and delivering their own QI initiatives found that participants had higher levels of knowledge after completing the programme and felt more confident in leading QI initiatives. Six months after programme, 62% had lead QI projects [29]. Compared to existing training programmes, MOOCs offer, at least in principle, an inexpensive and flexible way to train healthcare professionals about QI. This work will further contribute to evidence on whether large and diverse online learning environments are an effective way to teach people about quality improvement and equip them with the knowledge and confidence to design and implement QI projects in practice.

The QI MOOC was developed by academics and clinicians at the University of Bath, and delivered via the FutureLearn© platform. It is a 6-week online course 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 etc.) in quality improvement methods, and to build their confidence in participating, initiating and perhaps leading quality improvement projects. Since September 2016 and as of April 2019, there have been 17,416 joiners (someone who registers for a course), 10,662 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) [30] across 8 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 and skills in the workplace or professional practice after completing the course.

This protocol describes the design of a mixed methods study (pre-and post-MOOC surveys and semi-structured interviews) evaluating the effect and acceptability of the QI MOOC. Using a pre-post study design, data will be collected and analysed using a bespoke evaluation framework that draws from the RE-AIM and Kirkpatrick modelss to comprehensively assess the impact of the MOOC on participants' knowledge, skills and attitudes regarding QI and their confidence to engage and lead QI projects in their work environment or professional practice after completing the course. Feedback on the MOOC's content, format and structure will also be examined to identify areas for improvement for future course iterations as well as identify contextual features that facilitate or hinder designing and implementing QI projects in clinical environments.

METHODS AND ANALYSIS

MOOC development and delivery

The MOOC entitled, *"Quality Improvement in Healthcare: the Case for Change"* was developed by academics and clinicians/ consultants with expertise and leadership roles in QI and systems modelling and simulation in healthcare based at or affiliated with the Bath Centre for Healthcare Innovation and Improvement (CHI^2), School of Management, University of Bath, in collaboration with the West of England Academic Health Science Network. Hosted on the FutureLearn© platform, the course is primarily designed for people working in health and care organisations such as clinicians, allied health professionals, nurses, managers or administrators, as well as people with a general interest in health and social care organisations, such as service users and carers. The MOOC is in the process of getting 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 course 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. 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. Educators drew on their own clinical and academic practice and coaching, as well as published research in this area.

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 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 are able to purchase a course completion certificate as evidence of participation.

Table 1. Core topics each week of the MOOC course

Week of course	Topic	Content
1	Introduction to Quality Improvement (QI)	Quality improvement as a concept, historical context of QI in healthcare, underlying principles of quality improvement, challenges in healthcare settings
2	Quality Improvement approaches	Examples of QI approaches (e.g. PDSA- the model for improvement), LEAN, six sigma), QI initiatives implementations, microsystems to improve care for patients, and reducing delays
3	Putting patients at the heart of quality improvement and safety	What is person-centred care? Importance of patient experience, putting person-centred care into practice and patient safety
4	Evaluating Quality Improvement	The system of profound knowledge, measurement for improvement
5	Systems modelling in Quality Improvement	What is systems modelling and how it can help, modelling demand and capacity, computer simulation for improvement
6	Making the case for quality improvement	Mobilising system leadership, sustainability, next steps on the improvement journey

Study design

A pre-post design using mixed methods (surveys, semi-structured interviews) will be used to evaluate the impact of the QI MOOC on learners' knowledge, and perceived confidence in engaging in QI activities (see Fig.1).

Drawing on approaches used in previous MOOC evaluation studies [18 19 31], two comprehensive models, the RE-AIM and Kirkpatrick, will help to guide the current study [32-34]. Both models seek to appraise the efficacy and longer-term impact of interventions or training programmes beyond immediate course outcomes, to better understand how individuals apply their acquired knowledge and skills in practice. While there is overlap in the two models, their key elements are slightly different. RE-AIM comprises 5 evaluative dimensions, including Reach (participation rate within the target audience and participant characteristics), Efficacy (short-term impact of the intervention on key outcomes), Adoption (workplaces adopting the intervention), Implementation (extent to which the intervention is implemented in the real-world) and Maintenance (extent to which the programme is sustained over time). By contrast, the Kirkpatrick model encompasses the following 4 elements of assessment: Reaction (participants' responses to the intervention), Learning (extent to which participants acquire the intended knowledge, skills and confidence), Behaviour (extent to which knowledge and skills are applied in practice), and Results (overall success of the intervention or training in resolving problems and achieving organisations goals).

For the current study, we selected specific RE-AIM and Kirkpatrick dimensions that were considered to be most relevant and applicable for evaluating the QI MOOC. Table 2 outlines the data collection methods, timelines, and dimensions of RE-AIM and Kirkpatrick model to be used in the current study. The dimensions, 'Adoption' (RE-AIM), 'Implementation' (RE-AIM) and 'Results (Kirkpatrick) will not be used because they tend to focus on the impact of the intervention at the organisational (rather than individual) level which is beyond the scope

of this study. Future evaluation work of the QI MOOC will seek to assess its impact at the organisation level. The current study focuses on measuring impact at the participant or individual level.

With regard to RE-AIM, the focus will be on assessing 3 elements - *reach, effectiveness and maintenance* of the MOOC at the individual level. Evaluation of *reach* will be achieved by examining the recruitment and completion rates for the MOOC and collecting socio-demographic data pre-MOOC to determine learners' characteristics. Knowledge (self-report and objective) and perceived confidence in starting and leading QI initiatives will be measured pre-and post-MOOC to determine the *effectiveness* of the MOOC. *Maintenance* (sustainability) of the MOOC will be assessed using post-course survey data and semi-structured interviews conducted three months post-MOOC to understand the effect of the course over time and participants' future engagement with QI activities beyond course completion, such as the types of QI projects that participants engaged with, or led in the work place. The post-MOOC interviews will also explore perceived facilitators and barriers to setting up QI projects. The RE-AIM model was chosen because it is concerned with the longer-term impact of interventions in real world settings. This was considered important since we want to examine whether the MOOC equips learners with the knowledge, skills and confidence to participate, help initiate and perhaps lead a quality improvement project in practice once the course has finished.

Three levels from the Kirkpatrick model will be used to evaluate the MOOC, namely *reaction, learning and behaviour*. The post-course survey data and qualitative interviews (3 months post-MOOC) will explore learners' motivations for doing the course and their reactions to it, such as appraisal of the course format, design and structure, overall learning experience, the course's strengths and weaknesses, and how it could be improved. For the learning dimension, the survey data and semi-structured interviews will investigate a number of issues, including participants' attitudes and experiences of engaging with others on the course (collaborative or social learning), thoughts as to whether they had acquired sufficient knowledge about QI to apply in practice (higher order learning), perceptions as to whether they had a better grasp of how to address and tackle QI problems in their work practice (reflective learning), and think critically about the process of acquiring new knowledge, skills and confidence to apply in their professional practice (skills development). Lastly, participant's behaviour will be assessed through semi-structured interviews to explore whether participants reported applying their new skills, knowledge and confidence to inform others about QI and engage in QI activities. The Kirkpatrick model has previously been applied to MOOC evaluation studies [18 31] and was considered an appropriate tool to guide the evaluation of the current study.

Table 2. Evaluation framework methodology based on the RE-AIM and Kirkpatrick models – measures, data collection methods, timeline points

Evaluation model dimensions	Indicators	Description	Measures	Data collection methods	Timepoint of assessment
RE-AIM					
Reach		Extent to which intervention (MOOC) is reaching/ targeting the intended audience.	Socio-demographic information – age, country, gender, language, education level, employment.	Survey items	Pre-MOOC
Effectiveness		The impact of the MOOC on key outcomes - Knowledge & understanding of MOOC - Perceived Confidence in in QI	Knowledge assessment - subjective/ self-report and objective	Survey items	Pre and Post MOOC (immediate)
Maintenance (sustainable)		The longer-term impact of the intervention on key outcomes – future engagement with QI activities	Learner's confidence in their ability to design, implement, sustain QI activities. Barriers and facilitators to implementing QI projects.	Survey items Qualitative interview data	Post-MOOC (immediate and 3-month follow-up)

Kirkpatrick model					
Reaction	Self-efficacy and motivation	How did learners react to the course?	Self-efficacy in learner's ability to dedicate time and complete the course. Reasons for doing the MOOC.	Survey items Qualitative interview data	Pre and post-MOOC (immediate)
	Satisfaction & relevance		Satisfaction with learning experience and relevance to practice. How participants valued the course – strengths and weaknesses, areas of improvement Feedback on course content, layout, format and design.		
Learning	Course performance	The degree to which learners acquired knowledge, skills, attitudes and confidence.	Number of posts in the discussion forums, number of video views, quizzes completed	FutureLearn© data Survey items Qualitative interview data	Pre & Post-MOOC (immediate and 3-month follow-up)
	Collaborative learning		Attitudes and experiences of engaging with others on the course and asking for help. Collaborative learning – advantages and disadvantages		
	Higher order learning		Perceptions of whether higher order learning was achieved during the course – apply new		

			information to new situations, acquired new knowledge and understanding of QI		
	Reflective and integrative learning		Connected their learning to problems that could be addressed by QI, better understanding of how a QI problem might look from another person perspective (e.g. patient), learned something that changed the way they understood a concept or idea, connected ideas from the course to prior knowledge and experience.		
	Skills development		Capacity building - process by which learners gained knowledge, confidence and skills to engage in QI activities.		
Behaviour	Post-course practices	Ability to apply their new skills or knowledge in practice	Perceived self-efficacy, motivation, confidence in initiating/ implementing QI activities. Impact of the MOOC on work/ practice and ability to influence others in QI	Survey items Qualitative interview data	Post-MOOC (immediate and 3 month follow-up)

Study participants and recruitment procedure

All learners who enrol in the QI MOOC (via the FutureLearn© platform) will be invited to take part in the MOOC evaluation study (online Supplementary appendix 1), and will be provided with a participant information sheet informing them of the study procedures (online Supplementary appendix 2). Informed consent will be sought from learners who choose to participate in the study. The pre and post-course surveys will be integrated into the MOOC. We will aim to recruit at least 50 participants, ~10% of active learners in recent runs. However, if more than 50 consent to participate this will be allowed.

A sub-set of participants will be invited by email to take part in a semi-structured interview to explore in-depth how the MOOC impacted their learning and behaviour in practice after completing the course (online Supplementary appendix 3). We will aim to recruit and interview ~20 learners. Purposive sampling will be used to recruit a mixture of men and women from different age groups, professional backgrounds, organisations and countries will be recruited. The QI MOOC is designed for people working in health and social care organisations such as clinicians, junior doctors/ registrars, nurses, allied health professionals, managers, porters and caterers. Learners who took part in previous runs of the QI MOOC reflect this target audience so it is likely that the evaluation study will also reflect these groups.

Data collection

Online surveys (pre-MOOC and post-MOOC)

The pre-and post-course surveys will be integrated into the MOOC online system enabling learners to complete the surveys online once they have consented to the study.

The pre-MOOC surveys will collect socio-demographic variables, and identify learners' motivations for completing the course and any prior QI training and experience. Knowledge of QI (self-report and objective) and perceived confidence in designing and leading QI activities will be measured before and after the MOOC to determine the effect of the MOOC on these outcomes. Knowledge about QI was assessed using a 12-item multiple-choice test to measure core knowledge and understanding of QI that could be acquired from taking the course. Each question had five possible answers with one answer correct (supplementary appendix 4). Upon completion of the MOOC, a post-course survey will be administered to investigate participant's overall reactions to the course (content and design), their satisfaction with the learning experience, attitudes and experiences of engaging with others on the course, capacity building - acquisition of new knowledge, skills and confidence to lead QI projects, and thoughts on how the course could be improved.

Table 2 provides an overview of the different measures in accordance with the RE-AIM and Kirkpatrick models, and when they will be assessed (pre-MOOC, post-MOOC or 3 months post-MOOC).

Qualitative interviews

Semi-structured interviews will be conducted 3 months post-MOOC to explore in-depth the impact of the MOOC on participants' learning and behaviour in relation to designing, leading implementing QI activities, as well as identifying factors perceived as barriers or facilitators to implementing QI projects. Given the global nature of the MOOC and participants can be from countries around the world, interviews will be carried out through telephone or Skype

calls. It is anticipated that interviews will be no more than 1 hour long. All interviews will be recorded and transcribed verbatim by an independent transcription service.

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 designing and leading in QI projects. 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) [30]. For the analysis, we shall group participants into these different categories to identify differences between the groups.

In terms of the qualitative analysis, we will adopt an inductive and deductive approach whereby analysis will be driven by participant's responses and the study evaluation questions, respectively. Thematic analysis methods will be applied, with the RE-AIM and Kirkpatrick dimensions also guiding the data analysis [35 36].

Study ethics

During week 1 of the MOOC course, all learners will be invited to take part in the study and provided with a participant information sheet and consent form to read and sign online. Study data will be de-identified by allocating participants with a unique ID to ensure data is anonymous and confidential. All research data will be stored securely on the University of Bath network drives with security measures in place. A password protected participant database will be used to store patient identification number allocation. Only the researchers directly associated with the study will have access to the data. As appreciation for participant's time, 10 participants who complete both surveys will be randomly chosen to receive a £20 amazon voucher.

ETHICS AND DISSEMINATION

Ethics approval for this study was obtained from the University of Bath Human Research Ethics Committee (reference: 2958). The study will be conducted in accordance with University of Bath's Code of Good Practice in Research Integrity. Results of this study will be published in peer-reviewed journals, presented at national and international conferences, and disseminated through social media.

Patient and public involvement

There were no funds or time allocated for PP I in the design of the MOOC evaluation study so we were unable to involve patients or members of the public. Since the course started in 2016, changes have been made to the MOOC in response to feedback from learners. We intend to disseminate the results of the study to learners and will seek public involvement in the dissemination strategy.

Authors' contributions: SSL and CV conceived the QI MOOC evaluation study aims, methods and design. SSL drafted the first draft of the manuscript. CV, TH and AB reviewed

and commented on the first draft, and SSL addressed their feedback and suggestions. All authors approved the final manuscript.

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Competing interests: Three of the authors (AB, TW and CV) of this paper acted as Lead Educators of the QI MOOC.

Ethics approval: This study was approved by the University of Bath Human Research Ethics Committee (reference: 2958).

Data sharing statement: Requests for anonymised data can be made by contacting the corresponding author.

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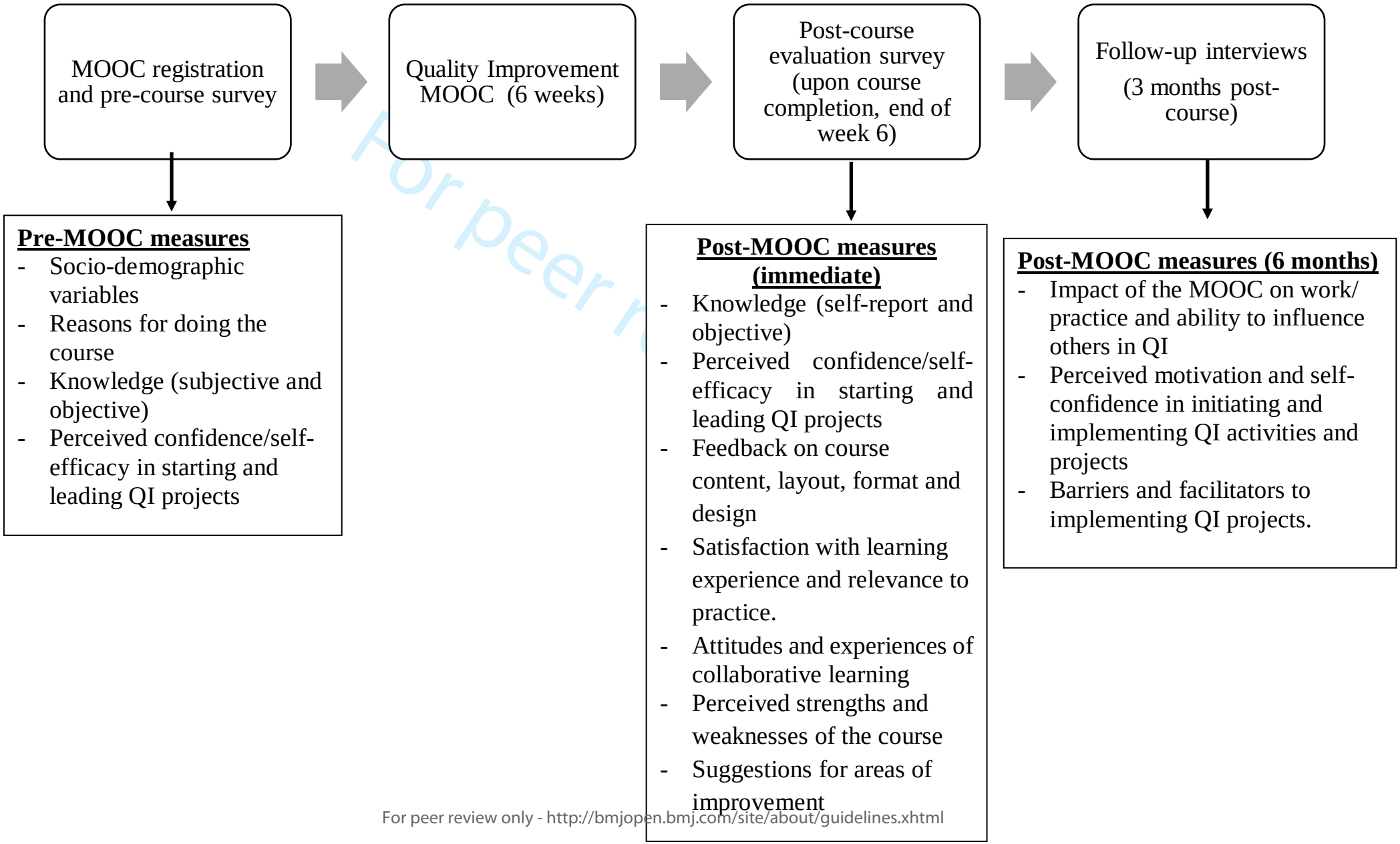
Figure legends/captions

Table 1. Core topics each week of the MOOC course

Table 2. Evaluation framework methodology based on the RE-AIM and Kirkpatrick models – measures, data collection methods, timeline points

Figure 1. Pre and post MOOC Evaluation: Flow of study procedure

Fig 1. Pre and post MOOC Evaluation: Flow of study procedure



Appendix 1: Study recruitment email
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

Dear Learner,

Thank you for your registering for the FutureLearn© MOOC, "Quality Improvement in Healthcare: the Case for Change."

We would like to invite you to take part in a study to evaluate the impact of the Quality Improvement MOOC on your understanding and confidence to engage in QI activities.

We will be inviting all learners (enrolled on this course) to take part in the study. Participation in the study will involve completing 2 surveys, one before the MOOC, and one after the MOOC. There will also be the opportunity to take part in a follow-up interview around 3 months after the MOOC to see whether the MOOC has impacted on your confidence to engage in QI initiatives in your workplace/ organisation. With permission, the interviews will be recorded and transcribed verbatim, and take about 30-45 minutes.

Participation in completely voluntary, and if you want to stop you can simply leave this page at any time. All responses will be anonymous. Your responses on the study survey will not be associated with your FutureLearn© account, and will not impact your progress on the course or future courses.

If you are happy to proceed and for us to use your responses, please complete this first short survey before you take part in the MOOC *(insert link to electronic online consent form and pre-MOOC survey)*. The survey should only take 10 or so minutes to complete, and will ask you some questions about yourself, your understanding of QI, and your confidence in participating in QI projects.

All the information collected will be stored and handled according to the University of Bath's code of good practice in research integrity policy. The findings from the survey will be published in peer-reviewed journals and presented at conferences.

At the end of week 6, we will invite you to take part in the second survey and the 3-month follow-up interview.

If you have any questions, please email Dr Sian Smith-Lickess: skl54@bath.ac.uk

Thank you very much,

Dr Sian Smith-Lickess & Professor Christos Vasilakis
Bath Centre for Healthcare Innovation and Improvement (CHI^2), School of Management, University of Bath, UK.

Please note that this is an independent research carried out by the University of Bath and your participation is subject to the University's own policies and terms. FutureLearn takes no responsibility for the contents or the consequences of your participation in this study. Your participation in the research has no effect on your course progress, marks or FutureLearn profile.

Appendix 2: Participant information sheet
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

UNIVERSITY OF BATH
SCHOOL OF MANAGEMENT

Participant Information Sheet

Quality Improvement in Healthcare MOOC Evaluation Study

We would like to invite you to take part in this study to help us to evaluate the Quality Improvement in Healthcare MOOC.

The research is being conducted by researchers at the Bath Centre for Healthcare Innovation and Improvement (CHI^2), School of Management, University of Bath, UK.

We have prepared some information to help you decide whether you would like to take part in the study and tell you about what participation will involve.

1. What is the purpose of the study?

This study aims to evaluate the effect of the Quality Improvement (QI) MOOC on building learner's knowledge, skills and confidence with engaging in QI activities after completing the course. The results from this study will also help us to understand how to improve the MOOC in future runs.

2. What does participation involve?

Taking part in this study will involve completing some survey questions online before and after completing the course. These questions will ask you about your QI knowledge and confidence in participating in QI activities. We will also ask for your feedback on the course and suggestions on how we can improve it. This questionnaire will take about 15 minutes to complete.

We would also like to conduct individual follow-up interviews (by telephone or skype) with around 20 participants to explore how the course influenced their participation in QI activities and projects. The interviews will last about 30-45 minutes and take place about 3 months after the course has finished, at a convenient date and time. Consent for this interview will be sought separately. With participant consent, the interview will be recorded and transcribed verbatim.

3. Do I have to take part in this study?

No. You do not have to take part in the study and can withdraw at any time without giving a reason. Withdrawing from the study will not affect your participation on the MOOC.

4. How do I take part?

If you would like to take part in this study, you will be able to consent online when you register for the MOOC. Anyone who has registered to take part in the QI MOOC can take part in the study.

Appendix 2: Participant information sheet
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

5. What are the potential benefits of taking part?

Taking part in this study will enable us to have a better understanding of how effective the MOOC is in relation to developing people's knowledge and skills in QI, and gives learners the confidence to participate in QI initiatives.

All participants will have the opportunity to be entered into a draw whereby 10 participants will be randomly chosen to receive a £20 amazon voucher.

6. What are the potential risks of taking part?

The inconvenience of your time to complete the survey questions and potentially the follow-up telephone interview (if consented) that participation requires.

7. What will happen to information about me?

To maintain confidentiality and anonymity, each participant will be given a unique identifier and data (survey, audio data and transcripts) will be securely stored in accordance with the University of Bath rules and regulations using password protected files.
All data will be kept strictly confidential and accessible only by University of Bath project administrators.

Please note : this is an independent research carried out by the University of Bath and your participation is subject to the University's own policies and terms. FutureLearn takes no responsibility for the contents or the consequences of your participation in this study. Your participation in the research has no effect on your course progress, marks or FutureLearn profile.

8. What will happen to the results?

We plan to publish the results in peer-reviewed journals, and present them at conferences. Please contact Professor Christos Vasilakis or Dr Sian Smith-Lickess, if you have any questions about the study.

Bath Centre for Healthcare Innovation and Improvement (CHI^2), School of Management, University of Bath, UK.

University of Bath | East Building | Claverton Down | BA2 7AY | UK
Email: skl54@bath.ac.uk | Tel: +44 (0) 7435 635 243

Appendix 3: Follow-up interview guide
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

Follow- up interview guide (3 months post-MOOC)

Aims

- Determine participant's perceived confidence to engage in QI activities, and design and implement projects
- Identify what participants valued about the MOOC
- Understand how the course impacted on behaviour and professional practice at work
- Identify any potential QI projects that participants have taken part in, or have designed and implemented
- Explore perceived barriers and facilitators to implementing QI projects

- **Perceived value of course participation**

Probes

- Motivators – why did you do the course?
- Did you get what you wanted from the course?
- Have you done distance learning before?
- How useful was the course? Why?
- What steps could be taken to improve the course for next time?
- What did you gain most from taking part in the MOOC?

- **Collaborative learning**

Probes

- Can you tell me whether you interacted with other learners on the course, or the course team/educators? (e.g. through discussion posts)?
- How did you find interacting with other learners on the course?
- Was there a particular aspect that made you feel really engaged?
- Was there a particular activity or resource that stood out for you, that you remember now?

- **Perceived impact of the MOOC**

We are interested to know whether you have been able to apply the knowledge and skills to your work/professional practice.

- Have you been able to apply what you learnt from the course? Why/ why not?
- Intention or initiation of QI activities/ projects in your department- if not, why?
- Specific examples of these and how they have worked (or did not work in practice)

Probes:

- Please tell us a bit more about the specific project and its aims?
- What was the problem you were trying to solve/ improve?
- How was this achieved (or not)?
- Experience of involving colleagues and patients, other stakeholders
- Steps to do this – design, deliver, implement, sustain
- Steps to ensure improvements are sustained?

- **Barriers and facilitators to QI success**

We would like to know your thoughts on the potential barriers/ challenges and facilitators to improving quality in healthcare – the factors influencing QI success

- What do you see are the barriers / challenges to participating in QI initiatives in your organisation (engaging, designing, implementing QI projects)?
- Strategies to overcome barriers?
- What has helped you to be engaged in QI initiatives in your organisation?
- What are the factors that facilitate (or could facilitate) QI success in your professional practice?

Appendix 4. QI Knowledge questions and answers

Purpose	Question	Options	Correct answer
1. Summary context of need for QI	Gaining a deeper and wider understanding of Quality Improvement is increasingly important because…	a. Delivery systems are complex. b. Clinical knowledge is advancing rapidly. c. Patients and families expect better care. d. However rich a country there is a finite limit on resources that can be allocated to healthcare e. All of these	e
2. To know the Institute of Medicine (IOM) definition of quality	Quality of healthcare is a wide ranging concept that should always include the consideration of…	a. Safety b. Cost c. Effectiveness and efficiency d. Safety, timeliness, effectiveness, efficiency, equity and person centredness e. Research	d
3. To know the Plan, Do, Study, Act (PDSA) cycle underpins all methods	Quality improvement methods have various components the one seen in all is…	a. The Plan Do Study Act (PDSA) cycle b. co production with patients c. 30_60_90 day routine d. pattern recognition e. all of these	a
4. To know a combination of measures is needed	The following measurement system will ensure that the team know that change is improving the system or not…	a. A previous years baseline b. Time ordered run charts c. Staff experience of doing work differently d. Patient experience feedback e. All of these	e
5. To refresh their minds of what is needed to understand formal system are a small part of success	The patient voice is vital when we are redesigning approaches to care. The following prevent us hearing what they say…	a. Ensuring patients stories are part of our work a. Should be undertaken by a small sub set of the team b. Using formal reporting systems c. Developing an inclusive approach d. Building in regular feedback to everyone	c
6. To know that leadership is local and distributed	Which of the following statements are correct?	a. A senior leader must give permission b. There is always a financial cost to improvement c. Leadership is focused in senior team members d. Patients can be effective leaders of improvement	d

		e. Learning comes from report writing and publication	
7. To know the place and character of this approach to systems understanding	The lens of profound knowledge…	a. is used at the end of an improvement project b. rarely enables an immediate single solution to be clear c. should be undertaken by a small sub set of the team d. is a swift task after some changes have been tested e. is only useful in technical process change	a
8. To know the principles of a good measurement strategy	Measurement for improvement strategies always include…	a. process, outcome and balancing measures b. outcome measures are sufficient c. the ability to undertake evaluative statistics such as p values etc d. process measures e. a focus on reporting to leaders only	a
9. To know the role of systems modelling in a QI project	We build mathematical and computer simulation models to…	a. to imitate the operation of a care system very precisely b. to predict with great accuracy what the changes will do in real life c. as part of every QI project d. to evaluate the likely impact of change on patients, staff and systems e. all of these	d
10. To be able to tell the difference between analytical and computer simulation models	Analytical (mathematical) models…	a. typically contain a lot of more detail than computer simulation models b. typically require fewer simplifying assumptions than computer simulation models c. in general better suited in projects where we have good reasons not to include a lot of organisational detail d. are worse the computer simulation models e. all of these	c
11. To know the components of good leadership	Sustaining an improvement developed through testing and learning will not be supported if…	a. it is incompatible with the values of the organisation b. the impact of the change on patients and staff is not well known c. the new way is more difficult than the old way d. leaders don't promote and recognise the effort taken e. all of these	e
12. To know the necessary approaches to spread	Spreading your improvement idea is more likely…	a. with a large pilot project b. when teams are involved early and can adapt if necessary c. with hard work you will make sure it spreads d. if you don't worry about local context, it is not relevant e. if the learning is put in a policy and implemented	b

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym YES
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry N/A
	2b	All items from the World Health Organization Trial Registration Data Set N/A
Protocol version	3	Date and version identifier YES
Funding	4	Sources and types of financial, material, and other support YES
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors YES
	5b	Name and contact information for the trial sponsor N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) N/A
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention YES
	6b	Explanation for choice of comparators N/A
Objectives	7	Specific objectives or hypotheses YES
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) YES

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained YES
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) YES
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered N/A
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended YES
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) YES
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations YES
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size YES

Methods: Assignment of interventions (for controlled trials)

Allocation:		
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol YES
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols YES
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol YES
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol YES
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) YES
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) N/A
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed N/A

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct YES
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor YES

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval YES
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) YES
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) YES
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable YES
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial YES
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site YES
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators YES
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers YES
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code YES

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates YES
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable YES

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Study design and protocol for a comprehensive evaluation of a UK massive open online course (MOOC) on quality improvement in healthcare

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Keywords:	MOOC, Massive Open Online Course, quality improvement, healthcare, Kirkpatrick, RE-AIM

Title: Study design and protocol for a comprehensive evaluation of a UK massive open online course (MOOC) on quality improvement in healthcare

Running title: Quality Improvement MOOC

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ABSTRACT

Introduction Massive Open Online Courses (MOOCs) offer a flexible approach to online and distance learning, and are growing in popularity. Several MOOCs are now available, to help learners build on their knowledge in a number of healthcare topics. More research is needed to determine the effectiveness of MOOCs as an online education tool, and explore their longer-term impact on learners' professional practice. We present a protocol describing the design of comprehensive, mixed-methods evaluation of a MOOC, 'Quality Improvement (QI) in Healthcare' which aims to improve learner's knowledge and understanding of QI approaches in healthcare, and to increase their confidence in participating, and possibly leading QI projects.

Methods and analysis A pre-post study design using quantitative and qualitative methods will be used to evaluate the QI MOOC. Different elements of the RE-AIM (reach, effectiveness and maintenance) and Kirkpatrick (reaction, learning and behaviour) models will be used to guide the evaluation. All learners who register for the course will be invited to participate in the QI MOOC evaluation study. Those who consent will be asked to complete a pre-survey to assess baseline QI knowledge (self-report and objective) and perceived confidence in engaging in QI activities. Upon completion of the course, participants will complete a post-survey measuring again knowledge and perceived confidence. Feedback on the course content and how it can be improved. A sub-set of participants will be invited to take part in a follow-up qualitative interview, three months after taking the course, to explore in-depth how the MOOC impacted their behaviour in practice.

Ethics and dissemination: The study has been approved by the University of Bath Human Research Ethics Committee (reference: 2958). Study findings will be published in peer-reviewed journals, and disseminated at conference and departmental presentations, and more widely using social media, microblogging sites and periodicals aimed at healthcare professionals.

Strengths and limitations of this study

- Application of the RE-AIM and Kirkpatrick models to capture the impact of the first UK-based QI MOOC on participants' knowledge and perceived confidence in participating in QI projects.
- Use of mixed methods to conduct a comprehensive evaluation of the QI MOOC and contribute to evidence on MOOC effectiveness in healthcare settings.
- 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.

Keywords: MOOC, Massive Open Online Course, quality improvement, healthcare, evaluation, Kirkpatrick model, RE-AIM, education

Word limit: 3,723 words (excluding tables, abstract and references)

INTRODUCTION

In an era of online education and distance learning, Massive Open Online Courses (MOOCs) provide a platform to disseminate information on a large-scale and reach a global audience with different disciplinary and cultural backgrounds [1]. MOOCs are generally offered for free, and developed by academics working in higher education institutes, in collaboration with professional and commercial organisations who host the MOOCs via their online platforms [2]. They have predominately been created in developed countries such as Australia, the United States, and the United Kingdom, although their potential in developing countries is increasingly recognised [3 4]. Most MOOCs use a variety of learning formats such as video lectures, online discussion, articles, recommended reading lists and self-assessments/ quizzes, to engage learners within a global virtual classroom setting [5].

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].

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 patients using virtual patients [19]. 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 learning[13], 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 family [19]. 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. [20 21]
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 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 models [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.

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) 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].

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 (CHI^2), 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 17,416 joiners (someone who registers for a course), 10,662 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.

Training healthcare professionals in QI using team-based learning has shown to be an effective way to influence knowledge and behaviour (Armstrong et al. 2012: Jones et al. 2015). For example, a project-based training programme to mentor and support learners in designing and delivering their own QI initiatives found that participants had higher levels of knowledge after completing the programme and felt more confident in leading QI initiatives. Six months after programme, 62% had lead QI projects [36]. Compared to existing training programmes, MOOCs offer, at least in principle, an inexpensive and flexible way to train healthcare professionals about QI. This work will further contribute to evidence on whether

large and diverse online learning environments are an effective way to teach people about quality improvement and equip them with the knowledge and confidence to participate in QI initiatives.

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 a follow-up semi-structured interview, was chosen to better understand the immediate and longer-term impact of the MOOC on a number of different outcomes.

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 understanding of QI approaches, and increase perceived confidence in participating in QI initiatives? (effectiveness)

The secondary research questions of the MOOC comprise the following:

- 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)

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 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.

Table 1. Core topics, related content and learning objectives of the MOOC course

Week of course	Topic	Content	Learning objectives
1	Introduction to Quality Improvement (QI)	Quality improvement as a concept, historical context of QI in healthcare, underlying principles of quality improvement, challenges in healthcare settings	Be able to identify what quality and process improvement entails, especially in a health and social care setting
2	Quality Improvement approaches	Examples of QI approaches (e.g. PDSA- the model for improvement), LEAN, six sigma), QI initiatives implementations, microsystems to improve care for patients, and reducing delays	Be able to discuss how quality improvement can help you deal with complexity in organisational systems and identify how to improve key areas without worsening others
3	Putting patients at the heart of quality improvement and safety	What is person-centred care? Importance of patient experience, putting person-centred care into practice and patient safety	Be able to explain how quality improvement can lead to better outcomes for staff and organisations, including customers and/or patients
4	Evaluating Quality Improvement	The system of profound knowledge, measurement for improvement	Be able to understand how to evaluate QI projects
5	Systems modelling in Quality Improvement	What is systems modelling and how it can help, modelling demand and capacity, computer simulation for improvement	Be able to explore how systems modelling and analytics techniques support quality improvement initiatives
6	Making the case for quality improvement	Mobilising system leadership, sustainability, next steps on the improvement journey	Be able to gain confidence to start and lead a quality improvement project within your organisation, identify how to access additional support, and get others to join with you in making improvements

Study design

A pre-post design using mixed methods (surveys, semi-structured interviews) will be used to evaluate the impact of the QI MOOC on learners' knowledge, and perceived confidence in engaging in QI activities (Figure 1).

Drawing on approaches used in previous MOOC evaluation studies [17 18 37], two comprehensive models, the RE-AIM and Kirkpatrick, will help to guide the current study [24-26]. While there is overlap in the two models, their key elements are slightly different. RE-AIM comprises 5 evaluative dimensions, including Reach (participation rate within the target audience and participant characteristics), Efficacy (short-term impact of the intervention on key outcomes), Adoption (workplaces adopting the intervention), Implementation (extent to which the intervention is implemented in the real-world) and Maintenance (extent to which the programme is sustained over time). By contrast, the Kirkpatrick model encompasses the following 4 elements of assessment: Reaction (participants' responses to the intervention), Learning (extent to which participants acquire the intended knowledge and confidence), Behaviour (extent to which knowledge is translated into practice), and Results (overall success of the intervention or training in resolving problems and achieving organisations goals).

For the current study, we selected specific RE-AIM and Kirkpatrick dimensions that were considered to be most relevant and applicable for evaluating the QI MOOC. Table 2 outlines the data collection methods, timelines, and dimensions of RE-AIM and Kirkpatrick model to be used in the current study. The dimensions, 'Adoption' (RE-AIM), 'Implementation' (RE-AIM) and 'Results (Kirkpatrick) will not be used because they tend to focus on the impact of the intervention at the organisational (rather than individual) level which is beyond the scope of this study. Future evaluation work of the QI MOOC will seek to assess its impact at the organisation level. The current study focuses on measuring impact at the participant or individual level.

With regard to RE-AIM, the focus will be on assessing 3 elements - *reach, effectiveness and maintenance* of the MOOC at the individual level. Evaluation of *reach* will be achieved by examining the recruitment and completion rates for the MOOC and collecting socio-demographic data pre-MOOC to determine learners' characteristics. Knowledge (self-report and objective) and perceived confidence in starting and leading QI initiatives will be measured pre-and post-MOOC to determine the *effectiveness* of the MOOC. *Maintenance* (sustainability) of the MOOC will be assessed using post-course survey data and semi-structured interviews conducted three months post-MOOC to understand the effect of the course over time and participants' future engagement with QI activities beyond course completion, such as the types of QI projects that participants engaged with, or led in the work place. The post-MOOC interviews will also explore perceived facilitators and barriers to setting up QI projects. The RE-AIM model was chosen because it is concerned with the longer-term impact of interventions in real world settings. This was considered important since we want to examine whether the MOOC equips learners with the knowledge and confidence to participate, help initiate and perhaps lead a quality improvement project in practice once the course has finished.

Three levels from the Kirkpatrick model will be used to evaluate the MOOC, namely *reaction, learning and behaviour*. The post-course survey data and qualitative interviews (3 months post-MOOC) will explore learners' motivations for doing the course and their reactions to it, such as appraisal of the course format, design and structure, overall learning

experience, the course's strengths and weaknesses, and how it could be improved. For the learning dimension, the survey data and semi-structured interviews will investigate a number of issues, including participants' attitudes and experiences of engaging with others on the course (collaborative or social learning), thoughts as to whether they had acquired sufficient knowledge about QI to apply in practice (higher order learning), perceptions as to whether they had a better grasp of how to address and tackle QI problems in their work practice (reflective learning), and think critically about the process of acquiring new knowledge and confidence to apply in their professional practice (capability). Lastly, participant's behaviour will be assessed through semi-structured interviews to explore whether participants reported applying their new knowledge to inform others about QI and engage in QI activities. The Kirkpatrick model has previously been applied to MOOC evaluation studies [17 37] and was considered an appropriate tool to guide the evaluation of the current study.

Table 2. Evaluation framework methodology based on the RE-AIM and Kirkpatrick models – measures, data collection methods, timeline points

Evaluation model dimensions	Indicators	Corresponding research question	Outcome measures	Data collection methods	Timepoint of assessment
Effectiveness	Knowledge and perceived confidence in QI	Primary research question – To what extent does the MOOC improve learner's knowledge and understanding of QI approaches and increasing perceived confidence in participating in QI initiatives?	Knowledge assessment - subjective/ self-report and objective	Survey items	Pre and Post MOOC (immediate)
Reach	Learners' characteristics	Secondary research question – What are the characteristics of the learners taking the MOOC?	Socio-demographic information – age, country, gender, language, education level, employment.	Survey items	Pre-MOOC
Reaction	Self-efficacy and motivation	Secondary research question – How did learners react to the course?	Reasons for doing the MOOC. Self-efficacy in learner's ability to dedicate time and complete the course.	Survey items Qualitative interview data	Pre and post-MOOC (immediate)

	Satisfaction & relevance		Satisfaction with learning experience and relevance to practice. How participants valued the course – strengths and weaknesses, areas of improvement Feedback on course content, layout, format and design.		
Learning		Secondary research question - How did the learners learn and how did they engage with other learners?		Survey items Qualitative interview data	Pre & Post-MOOC (immediate and 3-month follow-up)
	Collaborative learning		Attitudes and experiences of engaging with others on the course and asking for help. Collaborative learning – advantages and disadvantages		
	Higher order learning		Perceptions of whether higher order learning was achieved during the course – apply new information to new situations, acquired new knowledge and understanding of QI		
	Reflective and integrative learning		Connected their learning to problems that could be addressed by QI, better understanding of how a QI problem might look from another person perspective (e.g. patient), learned		

			something that changed the way they understood a concept or idea, connected ideas from the course to prior knowledge and experience.		
	Capability		The degree to which participants acquire the knowledge and confidence to engage in QI efforts based on their participation in the MOOC		
Maintenance (sustainable)	Longer-term effects of the MOOC	Secondary research question – What evidence suggests that learners retained knowledge acquired from the course?	Learner's confidence in their ability to design, implement, sustain QI activities.	Survey items Qualitative interview data	Post-MOOC (immediate and 3-month follow-up)
Behaviour	Post-course practices in work environment and professional	Secondary research question – What evidence suggests that the MOOC increased participation in QI initiatives?	Perceived self-efficacy, motivation, confidence in initiating/ implementing QI activities. Impact of the MOOC on work/	Survey items Qualitative interview data	Post-MOOC (immediate and 3 month follow-up)

	practice		practice and ability to influence others in QI Barriers and facilitators to implementing QI projects.		

Study participants and recruitment procedure

Figure 1 displays the flow of your study procedure. We propose to start the study in January 2020 of the QI MOOC, with follow-up interviews commencing around June 2020 (3 months post-MOOC completion). All learners who enrol in the QI MOOC (via the FutureLearn© platform) will be invited to take part in the MOOC evaluation study (online Supplementary appendix 1), and will be provided with a participant information sheet informing them of the study procedures (online Supplementary appendix 2). Informed consent will be sought from learners who choose to participate in the study (online Supplementary appendix 3). The pre and post-course surveys will be integrated into the MOOC (online Supplementary appendix 4 –post-course survey). We will aim to recruit at least 50 participants, ~10% of active learners in recent runs. However, if more than 50 consent to participate this will be allowed.

A sub-set of participants will be invited by email to take part in a semi-structured interview to explore in-depth how the MOOC impacted their learning and behaviour in practice after completing the course (online Supplementary appendix 5). 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. [38] Purposive sampling will be used to recruit a mixture of men and women from different age groups, professional backgrounds, organisations and countries. The QI MOOC is designed for people working in health and social care organisations such as clinicians, junior doctors/ registrars, nurses, allied health professionals, managers, porters and caterers. Learners who took part in previous runs of the QI MOOC reflect this target audience so it is likely that the evaluation study will also reflect these groups.

Data collection

Online surveys (pre-MOOC and post-MOOC)

The pre-and post-course surveys will be integrated into the MOOC online system enabling learners to complete the surveys online once they have consented to the study.

The pre-MOOC surveys will collect socio-demographic variables, and identify learners' motivations for completing the course and any prior QI training and experience. Knowledge of QI (self-report and objective) and perceived confidence in designing and leading QI activities will be measured before and after the MOOC to determine the effect of the MOOC on these outcomes. Knowledge about QI was assessed using a 12-item multiple-choice test to measure core knowledge and understanding of QI that could be acquired from taking the course (online supplementary appendix 6). Each question had five possible answers with one answer correct. Upon completion of the MOOC, a post-course survey (online supplementary appendix 4), using closed and open-ended questions, will be administered to investigate participant's overall reactions to the course (content and design), their satisfaction with the learning experience, attitudes and experiences of engaging with others on the course, capacity building - acquisition of new knowledge and perceived confidence to participate in (and possibly lead) QI projects, and thoughts on how the course could be improved.

Table 2 provides an overview of the different measures in accordance with the RE-AIM and Kirkpatrick models, and when they will be assessed (pre-MOOC, post-MOOC or 3 months post-MOOC).

Qualitative interviews

Semi-structured interviews will be conducted 3 months post-MOOC to explore in-depth the impact of the MOOC on participants' learning and behaviour in relation to designing, leading implementing QI activities, as well as identifying factors perceived as barriers or facilitators to implementing QI projects. Given the global nature of the MOOC and participants can be from countries around the world, interviews will be carried out through telephone or Skype calls. It is anticipated that interviews will be no more than 1 hour long. All interviews will be recorded and transcribed verbatim by an independent transcription service.

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.

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.

The interview data will be analysed by two qualitative researchers using the Framework 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 data[39]. The five stages of Framework are (1) familiarisation with data; a selection of 5 identified transcripts were independently read and themes identified, (2) developing a coding framework; a framework of themes and subthemes was created to code the data and further refined, (3) indexing; all transcripts were coded using the framework, (4) charting; the data were 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 were identified and discussed.

Study ethics

During week 1 of the MOOC course, all learners will be invited to take part in the study and provided with a participant information sheet and consent form to read and sign online. Study data will be de-identified by allocating participants with a unique ID to ensure data is anonymous and confidential. All research data will be stored securely on the University of Bath network drives with security measures in place. A password protected participant database will be used to store patient identification number allocation. Only the researchers directly associated with the study will have access to the data. As appreciation for

participant's time, 10 participants who complete both surveys will be randomly chosen to receive a £20 amazon voucher.

ETHICS AND DISSEMINATION

Ethics approval for this study was obtained from the University of Bath Human Research Ethics Committee (reference: 2958). The study will be conducted in accordance with University of Bath's Code of Good Practice in Research Integrity. Results of this study will be published in peer-reviewed journals, presented at national and international conferences, and disseminated through social media.

Patient and public involvement

There were no funds or time allocated for PP I in the design of the MOOC evaluation study so we were unable to involve patients or members of the public. Since the course started in 2016, changes have been made to the MOOC in response to feedback from learners. We intend to disseminate the results of the study to learners and will seek public involvement in the dissemination strategy.

Figures

Figure 1. Pre and post MOOC Evaluation: Flow of study procedure

Authors' contributions: SSL and CV conceived the QI MOOC evaluation study aims, methods and design. SSL drafted the first draft of the manuscript. CV, TW and AB reviewed and commented on the first draft, and SSL addressed their feedback and suggestions. All authors approved the final manuscript.

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Competing interests: Three of the authors (AB, TW and CV) of this paper acted as Lead Educators of the QI MOOC.

Ethics approval: This study was approved by the University of Bath Human Research Ethics Committee (reference: 2958).

Data sharing statement: Requests for anonymised data can be made by contacting the corresponding author.

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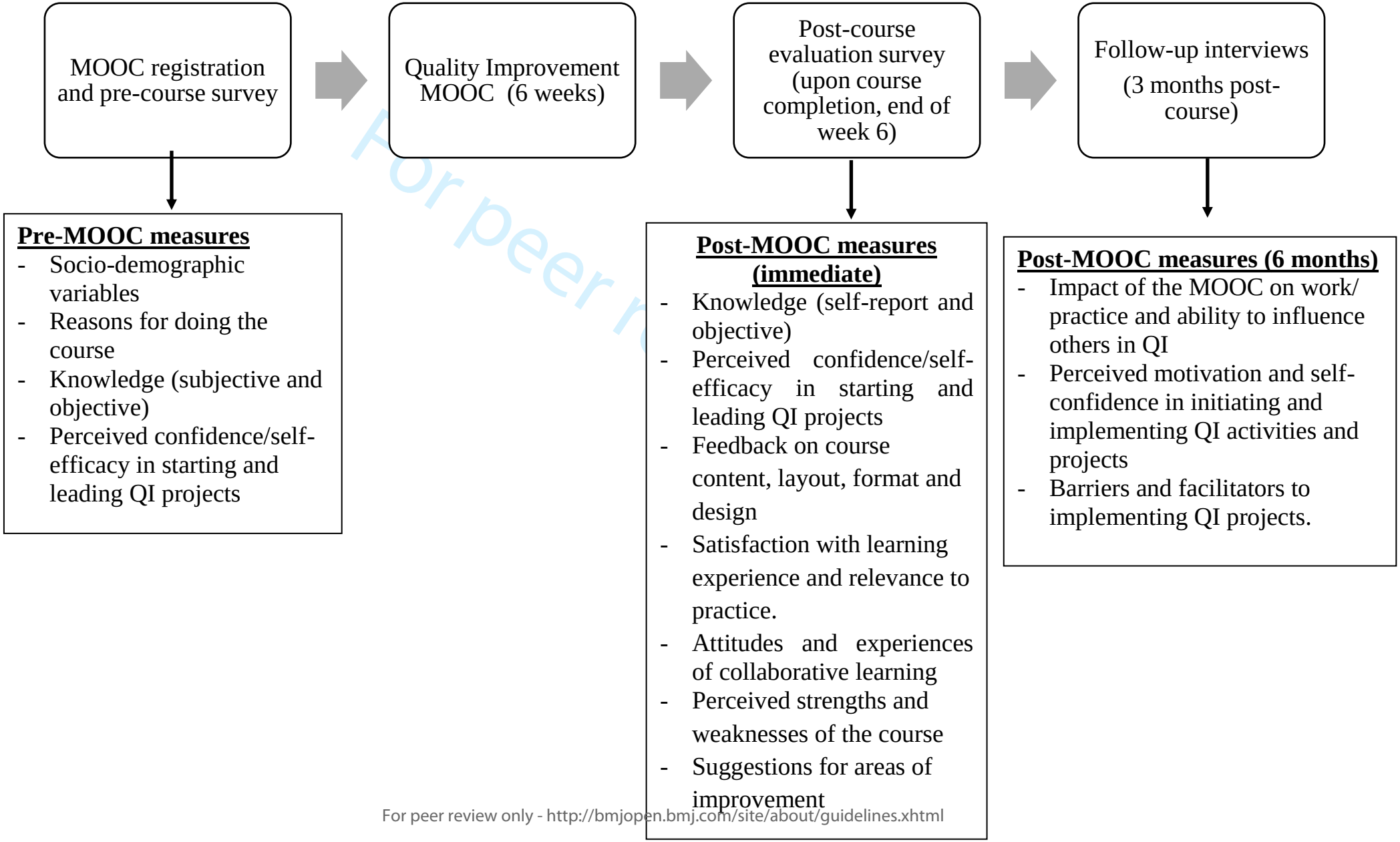
Figure 1. Pre and post MOOC Evaluation: Flow of study procedure



Appendix 1: Study recruitment email
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

Dear Learner,

Thank you for your registering for the FutureLearn© MOOC, "Quality Improvement in Healthcare: the Case for Change."

We would like to invite you to take part in a study to evaluate the impact of the Quality Improvement MOOC on your understanding and confidence to engage in QI activities.

We will be inviting all learners (enrolled on this course) to take part in the study. Participation in the study will involve completing 2 surveys, one before the MOOC, and one after the MOOC. There will also be the opportunity to take part in a follow-up interview around 3 months after the MOOC to see whether the MOOC has impacted on your confidence to engage in QI initiatives in your workplace/ organisation. With permission, the interviews will be recorded and transcribed verbatim, and take about 30-45 minutes.

Participation in completely voluntary, and if you want to stop you can simply leave this page at any time. All responses will be anonymous. Your responses on the study survey will not be associated with your FutureLearn© account, and will not impact your progress on the course or future courses.

If you are happy to proceed and for us to use your responses, please complete this first short survey before you take part in the MOOC *(insert link to electronic online consent form and pre-MOOC survey).* The survey should only take 10 or so minutes to complete, and will ask you some questions about yourself, your understanding of QI, and your confidence in participating in QI projects.

All the information collected will be stored and handled according to the University of Bath's code of good practice in research integrity policy. The findings from the survey will be published in peer-reviewed journals and presented at conferences.

At the end of week 6, we will invite you to take part in the second survey and the 3-month follow-up interview.

If you have any questions, please email Dr Sian Smith-Lickess: skl54@bath.ac.uk

Thank you very much,

Dr Sian Smith-Lickess & Professor Christos Vasilakis
Bath Centre for Healthcare Innovation and Improvement (CHI^2), School of Management, University of Bath, UK.

Please note that this is an independent research carried out by the University of Bath and your participation is subject to the University's own policies and terms. FutureLearn takes no responsibility for the contents or the consequences of your participation in this study. Your participation in the research has no effect on your course progress, marks or FutureLearn profile.

Appendix 2: Participant information sheet
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

UNIVERSITY OF BATH
SCHOOL OF MANAGEMENT

Participant Information Sheet

Quality Improvement in Healthcare MOOC Evaluation Study

We would like to invite you to take part in this study to help us to evaluate the Quality Improvement in Healthcare MOOC.

The research is being conducted by researchers at the Bath Centre for Healthcare Innovation and Improvement (CHI^2), School of Management, University of Bath, UK.

We have prepared some information to help you decide whether you would like to take part in the study and tell you about what participation will involve.

1. What is the purpose of the study?

This study aims to evaluate the effect of the Quality Improvement (QI) MOOC on building learner's knowledge, skills and confidence with engaging in QI activities after completing the course. The results from this study will also help us to understand how to improve the MOOC in future runs.

2. What does participation involve?

Taking part in this study will involve completing some survey questions online before and after completing the course. These questions will ask you about your QI knowledge and confidence in participating in QI activities. We will also ask for your feedback on the course and suggestions on how we can improve it. This questionnaire will take about 15 minutes to complete.

We would also like to conduct individual follow-up interviews (by telephone or skype) with around 20 participants to explore how the course influenced their participation in QI activities and projects. The interviews will last about 30-45 minutes and take place about 3 months after the course has finished, at a convenient date and time. Consent for this interview will be sought separately. With participant consent, the interview will be recorded and transcribed verbatim.

3. Do I have to take part in this study?

No. You do not have to take part in the study and can withdraw at any time without giving a reason. Withdrawing from the study will not affect your participation on the MOOC.

4. How do I take part?

If you would like to take part in this study, you will be able to consent online when you register for the MOOC. Anyone who has registered to take part in the QI MOOC can take part in the study.

Appendix 2: Participant information sheet
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QI MOOC Evaluation Study

5. What are the potential benefits of taking part?

Taking part in this study will enable us to have a better understanding of how effective the MOOC is in relation to developing people's knowledge and skills in QI, and gives learners the confidence to participate in QI initiatives.

All participants will have the opportunity to be entered into a draw whereby 10 participants will be randomly chosen to receive a £20 amazon voucher.

6. What are the potential risks of taking part?

The inconvenience of your time to complete the survey questions and potentially the follow-up telephone interview (if consented) that participation requires.

7. What will happen to information about me?

To maintain confidentiality and anonymity, each participant will be given a unique identifier and data (survey, audio data and transcripts) will be securely stored in accordance with the University of Bath rules and regulations using password protected files.
All data will be kept strictly confidential and accessible only by University of Bath project administrators.

Please note : this is an independent research carried out by the University of Bath and your participation is subject to the University's own policies and terms. FutureLearn takes no responsibility for the contents or the consequences of your participation in this study. Your participation in the research has no effect on your course progress, marks or FutureLearn profile.

8. What will happen to the results?

We plan to publish the results in peer-reviewed journals, and present them at conferences. Please contact Professor Christos Vasilakis or Dr Sian Smith-Lickess, if you have any questions about the study.

Bath Centre for Healthcare Innovation and Improvement (CHI^2), School of Management, University of Bath, UK.

University of Bath | East Building | Claverton Down | BA2 7AY | UK
Email: skl54@bath.ac.uk | Tel: +44 (0) 7435 635 243

Appendix 3: Online consent form
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

Online Consent Form for Quality Improvement MOOC Evaluation study

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You are invited to take part in a research study to evaluate the Quality Improvement (QI) in healthcare MOOC. This study will help us to understand if the course improves learners' knowledge and confidence to participate in QI projects, and identify ways in which we can improve the course. This study is being done by researchers from the Bath Centre for Healthcare Innovation and Improvement (CHI^2), School of Management, University of Bath.

As part of this study, you are invited to participate in a web-based online survey to evaluate the MOOC course.

ELECTRONIC CONSENT: Please select your choice below. Clicking on the "Agree" button indicates that…

- You have read the participant information sheet for the above study.
- You understand the purpose of the research, and what you will be asked to do.
- You understand that participation is voluntary and you are free to withdraw, without giving a reason.
- You understand that your responses will remain anonymous.
- You understand that the results of this study may be published, and that publications will not contain my name or any identifiable information.
- You understand this is an independent research survey carried out by the Bath Centre for Healthcare Innovation and Improvement (CHI^2), University of Bath, UK.
- Your participation in the study is subject to the University's own policies and terms.
- FutureLearn takes no responsibility for the contents or the consequences of your participation in this study. Your participation in the research has no effect on your course progress, marks or FutureLearn profile

☐ I agree to take part in the MOOC evaluation study
☐ I do not agree to take part in the MOOC evaluation study

FOLLOW-UP INTERVIEW
We would also like to conduct a follow-up interview with around 20 participants (by telephone or Skype) about 3 months after the course has finished. This interview will explore in more detail how the course influenced participants' confidence and ability to engage in QI projects. If you would like to take part in this follow-up interview, please indicate below that you agreed to be contacted by one of the researchers.

☐ I agree to be contacted about the follow-up interview 3 months after the course
If you agree to take part, please let us know your preferred way to be contacted
☐ Email (please provide your email address_____
☐ Phone number – insert phone number _____

☐ I do not agree to be contacted about the follow-up interview

Appendix 4: Post-MOOC survey
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

Post- MOOC study survey (online) – immediately after taking the course

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Thank you for taking the time to complete this survey. This survey will ask you some questions about your knowledge and understanding of QI, and your confidence in participating in QI projects since completing the course.

Please note : this is an independent research carried out by the University of Bath and your participation is subject to the University's own policies and terms. FutureLearn takes no responsibility for the contents or the consequences of your participation in this study. Your participation in the research has no effect on your course progress, marks or FutureLearn profile.

- **QI knowledge**

- **Self-report/subjective knowledge**

Having completed the course, I have good knowledge and understanding of how...We would now like to ask you some questions to see what you know about QI. Please tell us if you agree or disagree with the following statements (strongly agree to strongly disagree).

I have good knowledge and understanding of…

- how quality improvement can lead to better outcomes for staff, patients and organisations
- how to access additional support or resources, and get others to join with you in making improvements.
- how to start and lead a quality improvement project within my organisation.
- how to bring together a team to undertake quality improvement within my organisation

Appendix 4: Post-MOOC survey
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

Appendix 4: Post-MOOC survey
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

QI MOOC knowledge and marking scheme

Purpose / core knowledge	Question	Options	Correct answer
1. Summary context of need for QI	Gaining a deeper and wider understanding of Quality Improvement is increasingly important because…	a. Delivery systems are complex. b. Clinical knowledge is advancing rapidly. c. Patients and families expect better care. d. However rich a country there is a finite limit on resources that can be allocated to healthcare e. All of these	e
2. To know the Institute of Medicine (IOM) definition of quality	Quality of healthcare is a wide ranging concept that should always include the consideration of…	a. Safety b. Cost c. Effectiveness and efficiency d. Safety, timeliness, effectiveness, efficiency, equity and person centredness e. Research	d
3. To know the Plan, Do, Study, Act (PDSA) cycle underpins all methods	Quality improvement methods have various components the one seen in all is…	a. The Plan Do Study Act cycle b. co production with patients c. 30_60_90 day routine d. pattern recognition e. all of these	a
4. To know a combination of measures is needed	The following measurement system will ensure that the team know that change is improving the system or not…	a. A previous years baseline b. Time ordered run charts c. Staff experience of doing work differently d. Patient experience feedback e. All of these	e
5. To refresh their minds of what is needed to understand formal system are a small part of success	The patient voice is vital when we are redesigning approaches to care. The following prevent us hearing what they say…	a. Ensuring patients storiesare part of our work a. Should be undertaken by a small sub set of the team b. Using formal reporting systems c. Developing an inclusive approach d. Building in regular feedback to everyone	c
6. To know that leadership is local and distributed	Which of the following statements are correct?	a. A senior leader must give permission b. There is always a financial cost to improvement c. Leadership is focused in senior team members	d

Appendix 4: Post-MOOC survey
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

		d. Patients can be effective leaders of improvement e. Learning comes from report writing and publication	
7. To know the place and character of this approach to systems understanding	The lens of profound knowledge…	a. is used at the end of an improvement project b. rarely enables an immediate single solution to be clear c. should be undertaken by a small sub set of the team d. is a swift task after some changes have been tested e. is only useful in technical process change	a
8. To know the principles of a good measurement strategy	Measurement for improvement strategies always include…	a. process, outcome and balancing measures b. outcome measures are sufficient c. the ability to undertake evaluative statistics such as p values etc d. process measures e. a focus on reporting to leaders only	a
9. To know the role of systems modelling in a QI project	We build mathematical and computer simulation models to…	a. to imitate the operation of a care system very precisely b. to predict with great accuracy what the changes will do in real life c. as part of every QI project d. to evaluate the likely impact of change on patients, staff and systems e. all of these	d
10. To be able to tell the difference between analytical and computer simulation models	Analytical (mathematical) models…	a. typically contain a lot of more detail than computer simulation models b. typically require fewer simplifying assumptions than computer simulation models c. in general better suited in projects where we have good reasons not to include a lot of organisational detail d. are worse the computer simulation models e. all of these	c
11. To know the components of good leadership	Sustaining an improvement developed through testing and learning will not be supported if…	a. it is incompatible with the values of the organisation b. the impact of the change on patients and staff is not well known c. the new way is more difficult than the old way d. leaders don't promote and recognise the effort taken e. all of these	e
12. To know the necessary approaches to spread	Spreading your improvement idea is more likely…	a. with a large pilot project b. when teams are involved early and can adapt if necessary c. with hard work you will make sure it spreads d. if you don't worry about local context, it is not relevant e. if the learning is put in a policy and implemented	b

Appendix 4: Post-MOOC survey
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

Self- reported participation in QI initiatives (since course completion)

We'd like to find out how the course has effected learners' participation in QI activities.
Since completing the course, I have … Response options: Yes, No, I don't know, N/A

- 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

Perceived confidence in QI participation

Questions adapted from [29]

After completing the course, we'd like to know how confident are in participating in different QI activities. On a scale of 1- 10, how confident do you feel in your ability to… (1 = not at all confident, 10= very confident)

- participate in QI initiatives
- implement QI initiatives in my organisation
- evaluate QI initiatives in my organisation
- lead QI initiatives in my organisation
- teach QI initiatives in my organisation
- Completing the QI MOOC contributed to my career growth

On a scale of 1 to 10, please tell us how confident and familiar you are in different aspects of QI after taking the course… (0 = not at all, 10 = very confident)

- I am confident to talk about the importance and approach to ensuring quality healthcare
- I am confident to talk to others about the basics of at least one improvement method
- I am familiar with how patients can be involved in improvement and am confident in bringing this into my work/ participating as a patient in future
- I am familiar with how measurement matters in QI work and confident to talk about this with colleagues or at meetings
- I am comfortable with creating or using a run chart of real time data about a change we have made / seen
- I am confident to talk about systems and to hold back from solutions until we understand those systems better
- I am confident to talk about the usefulness of modeling an idea mathematically
- I am confident to work alone or with others to develop a QI project

Perceived capacity building

As a result of the course either during or since completing …(strongly agree, agree, neither agree or disagree, disagree, strongly disagree, N/A category, don't know)

- I have read other reports/ articles about QI
- I have thought about a problem with a new approach at work or in my out of work roles
- I have planned an improvement activity with others (meeting, data collection, PDSA for example)
- I have undertaken an improvement activity (meeting, data collection, PDSA for example)

Appendix 4: Post-MOOC survey
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

- I have learnt from being part of an improvement activity and feel more confident to participate and contribute
- I am now part of a regular improvement team at work

Feedback on the course

- Overall, how much did you enjoy your course experience? (Responses: A great deal, a lot, a moderate amount, a little, not at all)

Please tell us which of the following statements you agree with (strongly disagree, disagree, neither agree or disagree, agree, strongly agree)

- The course contained the information I needed
- The course was an appropriate length
- The course content was relevant to my profession or field
- The course content matched my expectations
- I was satisfied with the topics covered during the course
- The quizzes were a useful way to assess what I have learnt during the course
- My perspective has changed as a result of taking the course
- I've changed the way I do an aspect of my work as a result of taking the course
- I would recommend this course to friends and colleagues
- I've shared what I have learned with colleagues
- Taking the course has had a positive impact on my work and/or personally
- The course made good use of videos and other relevant resources
- The course was interactive and required me to think and respond to questions
- The group discussion posts were a useful way to interact with other learners
- I exchanged ideas or learnt from a discussion point made by another learner
- I was satisfied with the teaching style of the educators
- I felt able to ask for help or clarification from the educators/ course team if I needed it =

- Please tell us your thoughts and suggestions on how we could improve the course (e.g. was there any information not covered by the course that you think we should include)
  - What was the most enjoyable part of the course, and why? (open-ended)
  - What was the least enjoyable part of the course, and why? (open-ended)
  - Please tell us your thoughts and suggestions on how we could improve the course (e.g. was there any information not covered by the course that you think we should include)

Appendix 5: Follow-up interview guide
Version 1.0, 26/03/2019
QI MOOC Evaluation Study

Follow- up interview guide (3 months post-MOOC)

Aims

- Determine participant's perceived confidence to engage in QI activities, and design and implement projects
- Identify what participants valued about the MOOC
- Understand how the course impacted on behaviour and professional practice at work
- Identify any potential QI projects that participants have taken part in, or have designed and implemented
- Explore perceived barriers and facilitators to implementing QI projects

- **Perceived value of course participation**

Probes

- Motivators – why did you do the course?
- Did you get what you wanted from the course?
- Have you done distance learning before?
- How useful was the course? Why?
- What steps could be taken to improve the course for next time?
- What did you gain most from taking part in the MOOC?

- **Collaborative learning**

Probes

- Can you tell me whether you interacted with other learners on the course, or the course team/educators? (e.g. through discussion posts)?
- How did you find interacting with other learners on the course?
- Was there a particular aspect that made you feel really engaged?
- Was there a particular activity or resource that stood out for you, that you remember now?

- **Perceived impact of the MOOC**

We are interested to know whether you have been able to apply the knowledge and skills to your work/professional practice.

- Have you been able to apply what you learnt from the course? Why/ why not?
- Intention or initiation of QI activities/ projects in your department- if not, why?
- Specific examples of these and how they have worked (or did not work in practice)

Probes:

- Please tell us a bit more about the specific project and its aims?
- What was the problem you were trying to solve/ improve?
- How was this achieved (or not)?
- Experience of involving colleagues and patients, other stakeholders
- Steps to do this – design, deliver, implement, sustain
- Steps to ensure improvements are sustained?

- **Barriers and facilitators to QI success**

We would like to know your thoughts on the potential barriers/ challenges and facilitators to improving quality in healthcare – the factors influencing QI success

- What do you see are the barriers / challenges to participating in QI initiatives in your organisation (engaging, designing, implementing QI projects)?
- Strategies to overcome barriers?
- What has helped you to be engaged in QI initiatives in your organisation?
- What are the factors that facilitate (or could facilitate) QI success in your professional practice?

Supplementary online appendix 6

QI Knowledge questions and answers

Purpose	Question	Options	Correct answer
1. Summary context of need for QI	Gaining a deeper and wider understanding of Quality Improvement is increasingly important because…	a. Delivery systems are complex. b. Clinical knowledge is advancing rapidly. c. Patients and families expect better care. d. However rich a country there is a finite limit on resources that can be allocated to healthcare e. All of these	e
2. To know the Institute of Medicine (IOM) definition of quality	Quality of healthcare is a wide ranging concept that should always include the consideration of…	a. Safety b. Cost c. Effectiveness and efficiency d. Safety, timeliness, effectiveness, efficiency, equity and person centredness e. Research	d
3. To know the Plan, Do, Study, Act (PDSA) cycle underpins all methods	Quality improvement methods have various components the one seen in all is…	a. The Plan Do Study Act (PDSA) cycle b. co production with patients c. 30_60_90 day routine d. pattern recognition e. all of these	a
4. To know a combination of measures is needed	The following measurement system will ensure that the team know that change is improving the system or not…	a. A previous years baseline b. Time ordered run charts c. Staff experience of doing work differently d. Patient experience feedback e. All of these	e
5. To refresh their minds of what is needed to understand formal system are a small part of success	The patient voice is vital when we are redesigning approaches to care. The following prevent us hearing what they say…	a. Ensuring patients stories are part of our work a. Should be undertaken by a small sub set of the team b. Using formal reporting systems c. Developing an inclusive approach d. Building in regular feedback to everyone	c
6. To know that leadership is local and distributed	Which of the following statements are correct?	a. A senior leader must give permission b. There is always a financial cost to improvement c. Leadership is focused in senior team members d. Patients can be effective leaders of improvement	d

Supplementary online appendix 6

		e. Learning comes from report writing and publication	
7. To know the place and character of this approach to systems understanding	The lens of profound knowledge…	a. is used at the end of an improvement project b. rarely enables an immediate single solution to be clear c. should be undertaken by a small sub set of the team d. is a swift task after some changes have been tested e. is only useful in technical process change	a
8. To know the principles of a good measurement strategy	Measurement for improvement strategies always include…	a. process, outcome and balancing measures b. outcome measures are sufficient c. the ability to undertake evaluative statistics such as p values etc d. process measures e. a focus on reporting to leaders only	a
9. To know the role of systems modelling in a QI project	We build mathematical and computer simulation models to…	a. to imitate the operation of a care system very precisely b. to predict with great accuracy what the changes will do in real life c. as part of every QI project d. to evaluate the likely impact of change on patients, staff and systems e. all of these	d
10. To be able to tell the difference between analytical and computer simulation models	Analytical (mathematical) models…	a. typically contain a lot of more detail than computer simulation models b. typically require fewer simplifying assumptions than computer simulation models c. in general better suited in projects where we have good reasons not to include a lot of organisational detail d. are worse the computer simulation models e. all of these	c
11. To know the components of good leadership	Sustaining an improvement developed through testing and learning will not be supported if…	a. it is incompatible with the values of the organisation b. the impact of the change on patients and staff is not well known c. the new way is more difficult than the old way d. leaders don't promote and recognise the effort taken e. all of these	e
12. To know the necessary approaches to spread	Spreading your improvement idea is more likely…	a. with a large pilot project b. when teams are involved early and can adapt if necessary c. with hard work you will make sure it spreads d. if you don't worry about local context, it is not relevant e. if the learning is put in a policy and implemented	b

SPIRIT

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description
Administrative information		
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym YES
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry N/A
	2b	All items from the World Health Organization Trial Registration Data Set N/A
Protocol version	3	Date and version identifier YES
Funding	4	Sources and types of financial, material, and other support YES
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors YES
	5b	Name and contact information for the trial sponsor N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities N/A
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) N/A
Introduction		
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention YES
	6b	Explanation for choice of comparators N/A
Objectives	7	Specific objectives or hypotheses YES
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) YES

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained YES
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) YES
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered N/A
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) N/A
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) N/A
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial N/A
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended YES
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) YES
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations YES
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size YES

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial
Methods: Data collection, management, and analysis		
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol YES
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols YES
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol YES
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol YES
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses) YES
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) N/A
Methods: Monitoring		
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed N/A

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial N/A
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct YES
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor YES

Ethics and dissemination

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval YES
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators) YES
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) YES
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable YES
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial YES
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site YES
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators YES
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
	31b	Authorship eligibility guidelines and any intended use of professional writers YES
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code YES

Appendices

Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates YES
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable YES

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.