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Southampton and Bristol CTU efficient and innovative NIHR project final report:

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1. Title of Project

Presenting the evidence about digital tools for improving RCT recruitment and retention in online training packages to increase their uptake and the evidence base

2. Abstract

A previous NIHR CTU efficient studies project found that there was low usage of digital tools for recruitment and retention within RCTs among UKCRC-registered CTUs with frequently asked questions "What actually is a digital tool?"; "Can you give examples of these tools" and; "What support is available so staff could potentially use these tools within our CTU?". The aim of the current project was to 1) conduct a rapid review of studies evaluating digital tools, which would tackle these questions and 2) create an online training course for the NIHR community based on the findings of the previous study and the rapid review outcomes. The project resulted in a e-learning tool in the form of a MOOC (Massive Open Online Course) which can be accessed via Futurelearn (www.futurelearn.com).

3. Introduction

In our previous 2017 NIHR CTU efficient studies project *(User-focused research to identify the benefits of innovative digital recruitment and retention tools for more efficient conduct of randomised trials)* we found that there is low usage of digital tools among UKCRC-registered CTUs and identified common themes underlying this low usage rate (Blatch-Jones et al. 2020). When engaging with the UKCRC CTU network about our survey, the frequently asked

questions were: “What actually is a digital tool?”; “Can you give examples of these tools” and; “What support is available so staff could potentially use these tools within our CTU?”. To help trialists our previous project created a summary of the potential digital tools to use in different trial situations which could potentially assist recruitment and retention. To quantify and locate evidence about these tools, we also carried out a systematic evidence map which identified 101 eligible studies evaluating the effectiveness and efficiency of digital tools (Frampton et al. 2020).

As using digital tools is a relatively new area for many UKCRC CTUs, and it is anticipated that their use will become a lot more common also given the NIHR Digital Strategy, which aims to make the most of digital so that we can accelerate treatment and improve outcomes for patients, we thought it is important to help CTUs and other staff across the NIHR research infrastructure develop their understanding now of the available tools and provide them with training in how to use such tools.

Therefore, this follow-on NIHR CTU efficient studies project aims to build on the previous study by:

1. Carrying out a rapid review of a relevant sample of studies evaluating digital tools included in our previous systematic evidence map, to synthesise evidence for the effectiveness and efficiency of the tools and critically appraise the validity of this evidence, in a usable format.
2. Developing an online training course for the NIHR community on digital tools for recruitment and retention based on the results from the rapid review as well as the previous project.

The project aims to enable staff across the NIHR in CTUs, CRNs, RDSs, monitoring staff in NETSCC, NIHR grant applicants, funding board members, referees and others to not only locate and understand relevant evidence on digital tools for recruitment and retention, but also help them learn how to use the effective digital tools in their future trials, using real life examples.

The training in particular will support the NIHR community by disseminating know-how about adopting common digital tools for recruitment and retention, where the evidence supports their use. Where the evidence is lacking, it will facilitate a coordinated approach to creating primary research evidence (e.g. via the NIHR SWAT, i.e. Studies Within A Trial) programme, where a CTU could potentially randomise digital tools used within a trial).

2. Methods

The project set out to answer the following research questions and had 2 parts:

1. Which digital tools are available for recruitment and retention, what is the evidence for their effectiveness and efficiency, and how valid and reliable are the studies that provide this evidence? (**Part 1 - Evidence**)
2. Is it possible to develop and deliver an online training programme for CTU and other staff to equip them with sufficient knowledge and confidence to implement digital tools for recruitment? (**Part 2 - Training**)

3.1 Part 1 - Evidence

The rapid review assessed which digital tools are likely to be effective at improving recruitment and/or retention in RCTs in health. The evidence reviewed was identified from a comprehensive literature search performed for our previous research project, a systematic map of the evidence evaluating digital tools for recruitment and/or retention in trials (Frampton et al 2020). In that project a number of health and medical research databases were searched, including Medline, Embase and Web of Science, for the period 1990 to July 2018. Application of inclusion/exclusion criteria to the search results identified 105 relevant studies. We applied standardised descriptive keywords to each study and compiled all of the studies in a database. We summarised the key characteristics of all these studies to illustrate the breadth and depth of the evidence for digital tools in terms of factors such as medical specialism, healthcare setting, types of trial participants, and outcome measures.

The rapid review output was incorporated within Part 2 (Training).

2.1. Part 2 - Training

To enable the training of the NIHR community we developed e-learning tool in the form of a MOOC (Massive Open Online Course) which was informed by Part 1 (and other output from our previous (user focused) NIHR CTU efficient studies project). Its creation included the following components:

- **Scoping**: Discussions within the team about the most appropriate method to present the evidence from our surveys, qualitative work, systematic mapping and rapid review to a wide audience of relevant stakeholders given the timescale of the project. Discussion with digital learning experts to determine the most appropriate platform and course type according to the purpose, topic and target audience.
- **Development of content**: Discussions on what information should be included in the course and in what format as well as the length of the course and the expected learning outcomes. Development of text-based tailored content including tables and graphs. Development of scripts for video and audio recording. Development of discussion questions, activities and additional material. This process included face-to-face meetings plus teleconferences with digital learning, education and media specialists to ensure the training material was fit for purpose and suitable for an online course.
- **Peer review:** The draft content was peer reviewed by NIHR CTU staff not involved in the project, their feedback and comments were incorporated and an updated version of the course draft was developed.

As part of the MOOC (and as standalone YouTube videos) we also developed digital stories. The digital stories are in the form of short animated videos which are developed from the qualitative interviews conducted within the previous research study. Using an Integrated Participant Digital Storytelling (IPDS) approach, storytelling techniques were applied to synthesise data from multiple people into one representative narrative. The stories represented people's experiences with and views on the use of digital tools across the previously identified themes. Characters were developed based on participant roles and

characteristics and quotations were integrated into the story dialogue. The videos were created by an digital design and media freelancer.

Filming: Video and audio recordings of members of the team or external collaborators were made either face to face by the University of Southampton media team or self-recorded. All material was then edited by the media team for inclusion into the MOOC.

Implementation on an e-learning platform: All the MOOC course material was uploaded on the chosen online e-learning platform - Future Learn https://www.futurelearn.com..

3. Results and Conclusion

3.1. Part 1 - Evidence

The rapid review output was incorporated within the MOOC, with tabulations giving the detail of the validity of each digital tool. The table for each type of digital tool included details about the specific tool and alternative approach it was compared with, the outcome measure, population, location and context, a validity indicator and summary of issues and finally a link to the publication.

3.2. **Part 2 - Training -** Massive Open Online Course (MOOC)

A Massive Open Online Course (MOOC) was developed on the digital education platform FutureLearn (https://www.futurelearn.com) in collaboration with the University of Southampton Digital Learning team.

We followed an iterative developmental cycle between the project team and the University of Southampton digital learning, education and media specialists to ensure the evidence and content is presented in a way that is appropriate for the audience of the course but also accessible and compatible with the platform.

Key themes covered in the course were an overview of the many types of digital tools available, the evidence for recruitment and retention tools and recommendations for use. A

component on SWAT (Study Within A Trial) research was included in liaison with the Trial Forge (https://www.trialforge.org/) to help facilitate future digital tool research post-study and further advance the evidence of digital tools .

The course consists of 4 weeks as described below:

- Week 1: Introduction and evidence from the previous project
    - What are digital tools
    - Why you should use them
    - Who might benefit
    - Which tools are currently in use
- Week 2: Rapid review evidence for digital tools for recruitment
    - Websites
    - Social media
    - Search engines
    - Automated screening
- Week 3: Rapid review evidence for digital tools for retention
    - Emails
    - Text messages
- Week 4: Summary and conclusions
    - The case for using digital tools
    - Quality and validity
    - Recommendations for use
    - Studies Within A Trial (SWATs)

The course uses a combination of text-based information, tables, graphs and short videos. For example, the evidence about the effectiveness of specific tools for recruitment and retention was presented in tables with a voiceover explaining the table. Activities were also included to make the course more interactive and engaging, such as a discussion board and discussion questions throughout, quizzes and other exercises. Links and attachments for further reading have been included for participants who wish to learn more about the digital tools presented as well as other useful information.

Four animated digital stories representing the themes from the qualitative study were developed. Story 1 focussed on the potential benefits of using digital tools, story 2, the potential obstacles and risks, story 3, ensuring inclusivity and engagement and story 4, consideration of security, legitimacy and transparency. The stories were told by multiple characters representing a range of patient and public representatives, trialists, funding bodies and ethical committee members. One story was embedded within each MOOC training week. The videos are also available to view independently on you-tub.

The course development has been completed and is currently being reviewed by FutureLearn before going live on the platform. The course will be accessible for sign-up in September 2021 on this link https://www.futurelearn.com. The course is expected to start in October 2021 and run for 4 weeks during which a member of the team will facilitate the discussion and monitor progress. Course feedback as well as participant comments will be collected during this time to decide whether any updates are required.

We have made the course free to NIHR infrastructure and intend to disseminate across the network (such as via UKCRC, CRN and RDS newsletters/adverts).

Future plans

Once the 1st course has completed the MOOC will be available to all via FutureLearn. As mentioned we also intend to make the digital stories available via You-tube. By linking with Trial Forge (and including a section on SWATs in the MOOC) we anticipate this will help facilitate the UKCRC Clinical Trials Units to undertake future SWATs within their NIHR funded trials to further create evidence for digital tools which can be used in the future to potentially update the MOOC in the future.

Conclusion:

We believe that the course, supported by the rapid review evidence, has the potential to give the NIHR community the background and skills to adopt effective digital tools into their research and trial management practice and encourage them to run more SWATs to evaluate these tools. This will result in increased recruitment and retention rates across the NIHR trial

portfolio. The course could also enable an NIHR network supporting co-ordinated investigation of new digital tools in the future via primary research.

4. Dissemination

A journal paper will be published with the methodology and output of the rapid review.

A paper will also be written on the development of the MOOC in the context of education and multidisciplinary work. It will present the course developmental process, the potential to use MOOCs to educate clinical researchers and challenges and lessons learned from working in a multidisciplinary team.

The MOOC will be disseminated to relevant stakeholders including the NIHR, RDS, Trial Forge and CTU network.

5. Acknowledgments

Project team

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6. References

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7. Appendices

No appendices to include.

8. Conflict of Interest

The authors have no conflict of interest to report.