This is a repository copy of *Videoconferencing for site initiations in clinical studies: Mixed methods evaluation of usability, acceptability, and impact on recruitment*.

White Rose Research Online URL for this paper:
http://eprints.whiterose.ac.uk/86597/

Version: Accepted Version

Article:

Title: Videoconferencing for site initiations in clinical studies: Mixed methods evaluation of usability, acceptability, and impact on recruitment

Running head: Videoconferencing for clinical study initiations

Authors:

Rebecca Randell[1]*, email: r.randell@leeds.ac.uk, tel: +44 (0) 113 343 1337

Michael R. Backhouse[2], email: m.r.backhouse@leeds.ac.uk

E. Andrea Nelson[1], email: e.a.nelson@leeds.ac.uk

[1]School of Healthcare, Baines Wing, University of Leeds, Leeds LS2 9UT, UK

[2]Leeds Institute of Rheumatic and Musculoskeletal Medicine, University of Leeds, 2nd Floor, Chapel Allerton Hospital, Chapeltown Road, Leeds LS7 4SA, UK

*Corresponding author

Abstract

Background: A critical issue for multicentre clinical studies is conducting site initiations, ensuring sites are trained in study procedures and comply with relevant governance requirements before they begin recruiting patients. How technology can support site initiations has not previously been explored.

Objective: This study sought to evaluate use of off-the-shelf web based videoconferencing to deliver site initiations for a large national multicentre study.

Methods: Participants in the initiations, including podiatrists, diabetologists, trial co-ordinators, and research nurses, completed an online questionnaire based on the System Usability Scale (SUS) (N=15). This was followed by semi-structured interviews, with a consultant diabetologist, a trial coordinator, and three research nurses, exploring perceived benefits and limitations of videoconferencing.

Results: The mean SUS score for the videoconferencing platform was 87.2 (*SD* = 13.7), suggesting a good level of usability. Interview participants perceived initiations delivered by videoconferencing as being more interactive and easier to follow than those delivered by teleconference. In comparison to face-to-face initiations, videoconferencing takes less time, easily fitting in with the work of staff at the local sites. Perceptions of impact on communication varied according to the hardware used.

Conclusion: Off-the-shelf videoconferencing is a viable alternative to face-to-face site initiations and confers advantages over teleconferencing.

INTRODUCTION

Properly conducted clinical studies are essential for the application of evidence based healthcare (1). Multicentre studies, where more than one independent centre collaborates in the tasks of enrolling and following study participants (2), are important to increase both recruitment rates and the external validity of findings.

A particular challenge in the conduct of multicentre studies is ensuring that sites are appropriately trained in study procedures and comply with relevant governance requirements (3). To address this challenge, all sites that are participating in a study are required to undergo an initiation process before they can begin recruiting patients to the study (4). Site initiations typically cover everything from governance requirements, study specific requirements such as patient eligibility, study specific procedures, and randomisation etc. through to data management issues such as how to complete and return the case report forms (CRFs), and adverse event reporting. Effective processes for communicating this information are essential for the success of the study; failure in adequately communicating these points could result in data being collected on ineligible patients, failing to comply with legislation, inconsistent application of the intervention, and missing data, all of which not only represent a waste of resources but could threaten patient safety and the validity of the study (5). Delays in this process reduce the time subsequently available within the study for recruitment of patients. Additionally, site updates may be required if there is an amendment to the study protocol. Timeliness of the delivery of such updates is of particular importance when protocol amendments are made due to safety concerns that have arisen. Site initiations and updates are typically delivered through on-site visits but these can be costly in terms of time and travel expenses,

particularly in studies covering wide geographical areas, with a subsequent environmental impact (6). Teleconferences have been used as an alternative method of delivery but the absence of face-to-face contact may have a negative impact on communication.

One of the objectives of clinical research informatics (CRI) is 'to optimise the design and conduct of clinical research' (7). While attention within CRI has been given to recruitment of patients to clinical studies (8) and electronic collection, storage, and management of study data (9-13), how technology can support the site initiation process in multicentre studies has not been explored, despite this being a critical issue in relation to recruitment of patients and subsequent success of the study. As part of the CODIFI study, which assessed concordance between different wound sampling techniques in patients with infected diabetic foot ulcers, we delivered site initiations and updates through web based videoconferencing (14). We considered this would allow us to cut time and travel costs in comparison to on-site visits while providing face-to-face communication that would facilitate more effective two-way communication in comparison to teleconferencing. To evaluate the use of web based videoconferencing for this purpose, we invited participants in the site initiations and updates to complete a questionnaire survey and participate in a follow up telephone interview. Our aim was to explore participants' experience of using the technology and its acceptability to participants as a method for receiving site initiations and updates. To our knowledge the use of videoconferencing to deliver site initiations is novel and has not previously been reported. Below we first consider existing studies of videoconferencing within the health informatics literature and more widely, before describing our study methods and presenting our results. We conclude the paper by

discussing the implications of our findings for future research and for those wishing to use videoconferencing in support of site initiations and updates.

Videoconferencing in healthcare

Videoconferencing is not a new technology (15, 16) and has been in use in healthcare for more than 15 years (17). However, to our knowledge, only one study has previously explored the use of videoconferencing to facilitate the conduct of multicentre studies (3). Videoconferencing, in combination with telephone, email, and in-person visits, was used to support: standardisation of study processes, with the trial coordinator using videoconferencing to assess patients; patient management; clinical follow-up and monitoring of patients; and writing up the results for publication. However, site initiations were conducted in person, because the study authors considered that initial personal contact between the participants was necessary to develop rapport before introducing videoconferencing. While regular updates were provided by email, occasionally videoconferencing and telephone were used when immediate feedback on updates was required.

Other studies of videoconferencing within health informatics cover a broad spectrum of clinical applications, being concerned with communication between healthcare professionals and patients (18, 19), communication between two or more healthcare professionals (20-25), and communication for the purpose of education and training of healthcare professionals (17, 26, 27). Demeris et al. (18) describe the use of videoconferencing for remote dermatology consultations. Comparing face-to-face and remote dermatology consultations, they found patterns of communication were similar, with no apparent negative consequences for the quality of communication.

There was no significant difference in the duration of consultations in the two conditions, although there was a significant difference in the percentage of consultations in which general informal talk was observed, being more frequently observed in the remote consultations. Kane and Luz (22) studied the use of videoconferencing in the context of multidisciplinary team (MDT) meetings where MDT members were geographically dispersed and found that the overall structure for the discussion of a case was unaffected by the use of videoconferencing. However, in comparison to co-located MDT meetings, there was increased time spent in discussion of cases, fewer changes of speaker with speakers talking uninterrupted for increased time (suggesting a less natural flow of conversation), and fewer informal exchanges.

Some studies of videoconferencing within health informatics have used highly customised videoconferencing systems specially designed for the individual context. For example, this has included multiple cameras configured for the particular locations, shared access to multiple sources of data such as x-rays, and sometimes additional technology, e.g. a pen and tablet display system (19). The creation and use of such 'blended interaction spaces' (28) is motivated in part by early studies from other fields that point to the challenges of video-mediated communication. While use of videoconferencing, as opposed to teleconferencing, is based on the assumption that there is value for participants in a meeting to be able to see as well as hear each other, a study comparing videoconferencing with co-located conversations and audio-only conversations found that videoconferencing conferred no benefits over the audio-only condition, although participants perceived the visual access provided by videoconferencing to be important and beneficial (16). Heath and

Luff (15) describe the ineffectiveness of gesture and other forms of body movement such as gaze when communicating through video, with the consequence that speakers may delay or even abandon an utterance due to failing to obtain the relevant response from a recipient. Other studies suggest that while videoconferencing can provide benefits in terms of efficiency, the impressions that people form of remote others are less positive than impressions that are formed in face-to-face meetings (29).

The creation of sophisticated videoconferencing systems, or even the installation of specific hardware, is an approach that is not feasible for occasional (possibly one off) communication with a study site over a limited time period. However, use of off-the-shelf web based videoconferencing technology may result in communication challenges similar to those experienced in early evaluations of videoconferencing (15, 16). The objective of the present study was to explore the perceptions of the participants in the site initiations and updates of the impact of videoconferencing on communication, as well as their perception of the usability of the technology, in order to determine the acceptability of this as a means of delivering site initiations and updates.

METHODS

CODIFI recruited 400 patients from 26 sites across England. It assessed concordance between microbiological results obtained from a wound swab and a small piece of tissue removed from the same area of the wound bed. A protocol amendment was released after the study had opened to recruitment, following additional funding, which enabled sites to complete a 12 month casenote review and

some sites to collect a second swab for Polymerase Chain Reaction analysis through a commercial partner.

Adobe Connect (Adobe Systems, San Jose, California, USA), a web based videoconferencing platform that allows simultaneous delivery of PowerPoint presentations, was used for providing remote site initiations and updates. For the site initiations, the study team decided to do face-to-face initiations to local sites while they became familiar with the Adobe Connect technology. Consequently, videoconferencing was used for site initiations for 11 of the 26 sites, and then updates to all 26 sites (see Figure I for a summary of study steps with number of sites/participants). Prior to the initiations and updates via videoconferencing, sites were sent detailed step by step instructions for logging into Adobe Connect. Test presentations were arranged to ensure local firewalls permitted access to Adobe Connect and to ease any concerns about the technology. As this was a pragmatic observational study, system configurations varied depending on the facilities available at different sites with no additional hardware provided through the study and with the study team having no control over the configurations used. Sites with a webcam and microphone were able to use these, therefore enabling full two-way videoconferencing. Where sites did not have access to a microphone, we used a telephone in conjunction with the videoconferencing, with sites communicating through a speaker phone. Sites were encouraged to project images onto a screen to enable adequate visualisation of the presentation slides but, more often, a standard desktop computer was used. One site participated using an iPad.

[Figure I should go approximately here]

8

The site initiation covered the background to the study, guidelines for clinical trial processes, and key study management issues such as the processes for recruitment, consent, registration, CRF completion, and data transfer. Additionally, instructional videos of the techniques for collecting the different samples were streamed live during the presentation. In updates following the protocol amendment, how to package an additional sample for a commercial lab was demonstrated using the webcam.

Questionnaire survey

To evaluate the use of web based videoconferencing as a method for remotely delivering site initiation training and updates, we created an online questionnaire based on the System Usability Scale (SUS) questionnaire. We chose to use the SUS because it is a validated tool that is technology agnostic, meaning that it can be used to assess a wide range of technologies, and it is relatively quick and easy to complete (30). The questionnaire was composed of 10 statements scored on a 5-point scale of strength of agreement (where 1 = strongly disagree and 5 = strongly agree) designed to capture respondents' perceptions of the usability of a technology. The questionnaire asked respondents to record their gender and role and to rate their confidence in using a computer on a 7-point scale (where 1 = not confident at all and 7 = very confident). The questionnaire also provided a space for participants to record additional comments about their experience of using the videoconferencing tool.

During site initiations to three of the sites and updates to all 26 sites, we introduced the survey. This was followed by an email to all who participated in the initiation/update, with an invitation to participate and a link to the survey. Participation in the survey was anonymous, unless participants chose to provide their contact details in order to take part in the interview study.

The SUS data were analysed to provide an overall rating per participant using the standard methodology for the questionnaire (31). SUS scores can range from 0 to 100, where higher scores indicate better usability. Scores of 70 or above are considered acceptable, with better products scoring in the high 70s or above (30). Thematic content analysis was used for analysis of the free text comments. Because the survey was anonymous, it was not possible to analyse the responses by site to allow for cross-site comparison.

Telephone interviews

Following the questionnaire survey, we contacted via email those respondents who had provided contact details and invited them to participate in a brief semi-structured telephone interview. Interview questions explored what participants saw as the benefits and limitations of videoconferencing for site initiations and updates in comparison to face-to-face and teleconference site initiations and updates. Probes were developed based on the free text comments received via the survey. All interviews were audio recorded and later transcribed.

An iterative approach was taken to data collection and analysis, to allow the collection of further data on emerging themes in subsequent interviews. Anonymised

transcripts were entered into NVivo 10, software for qualitative data analysis. Data were analysed using thematic content analysis with codes developed inductively. Matrix displays were used to identify patterns in the data (32).

RESULTS

Use of videoconferencing enabled initiations to be conducted at geographically distant sites on the same day. Use of this method expedited the set up phase of the study. Consequently, the study opened to recruitment two months ahead of schedule, enabling us to maximise the percentage of the study time in which recruitment could take place, and recruitment was ahead of target for the 14 months from November 2011 to December 2012. The technology also enabled faster roll out of the subsequent protocol amendment. While we did not conduct inferential statistical analysis, there were no obvious differences between sites that received a face-to-face site initiation and those that received a site initiation via videoconferencing in the adequacy of their data collection procedures or the completeness of the CRFs, leading the study team to conclude that use of videoconferencing had no negative impact on participants' understanding of the information that was communicated.

Below we present the results of the questionnaire survey before presenting the findings from the interviews, organised according to key themes.

Questionnaire survey

Fifteen responses to the survey were received and nine respondents provided free text comments. One podiatrist, two diabetologists, one trial co-ordinator, and 11

research nurses completed the survey. Eleven of the 15 respondents were female. The mean rating for confidence in computer use was 6.6 (range 5-7). As responses to the survey were anonymous, unless respondents chose to provide their contact details, it is not possible to report how many sites participated in the survey. However, nine respondents did provide their contact details and all were from different sites, indicating that a minimum of nine sites participated in the survey.

The mean SUS score for Adobe Connect was 87.2 (SD = 13.7), suggesting high usability. This was supported by the free text comments. Three respondents commented on the ease of use of the system:

'All the team thought it was great and very simple to use.' (Research nurse 1)

'I am not a technology wizard but found the system easy to use.' (Research nurse 3)

'Getting connected […] was very straight forward and it is very easy to use.' (Research nurse 4)

One respondent commented on the difficulties of having multiple participants sat around a single desktop computer. One site had also had difficulty getting their IT department to allow access to Adobe Connect.

One respondent suggested that rapport would be better with a face-to-face initiation. Only one respondent commented on the benefits of being able to see the presenter:

'I found it useful as you can see the person on the other end and they can demonstrate, show study materials to us to familiarise with them.' (Research nurse 4)

One respondent questioned whether the system would be appropriate for more complex studies but suggested that videoconferencing could be used in combination with face-to-face site initiations.

Telephone interviews

Five participants, from five different sites, were recruited to take part in the interviews. The interview participants were three research nurses, one consultant diabetologist, and one trial coordinator. All interviewees had previous experience of participating in multicentre studies and had previously mainly experienced face-to-face site initiations. Two of the interviewees (Research nurse 3 and Trial coordinator) had participated both in the site initiation and update by videoconferencing, while the other interviewees had received a face-to-face initiation and the update by videoconferencing. Four of the five interviewees participated using a standard National Health Service (NHS) owned desktop computer, only one of which had a webcam, and one interviewee participated using an iPad. Information about the system configuration experienced by each interviewee is provided in Table I.

[Table I should go approximately here]

Acceptability

Three interviewees were very positive about the experience of using videoconferencing:

'It was fantastic… I think it's a fantastic system.' (Consultant diabetologist)

'Everybody was sort of like, oh this really good, this has worked really well.' (Research nurse 1)

'It was very good.' (Trial coordinator)

One of the research nurses preferred face-to-face site initiations but saw videoconferencing as an 'acceptable alternative' and described finding the presentation 'very easy to follow', while another research nurse saw it as no better or worse than a face-to-face site initiation. All interviewees perceived videoconferencing as preferable to telephone only site initiations.

Impact on communication

Three interviewees described the disadvantage of videoconferencing in comparison to face-to-face site initiations as having less opportunity to build a relationship with the study team:

'I suppose one of those sort of things is actually knowing, or just having some contact with the personnel and building up that relationship. You know, yes it's great but you know, we were able to see Mike [the presenter] and you know, but he couldn't see us and I don't know how he felt about that, you know, talking to a big black hole.' (Research nurse 1)

However, one interviewee commented on the value of being able to see the presenter in terms of building rapport:

'It's more like you're actually in the room […] Because sometimes when you're all round a conference phone it's a little bit anonymous.' (Research nurse 3)

The two interviewees who had webcams talked about the benefit of the presenter being able to see them in terms of establishing rapport:

'Body language is everything.' (Consultant diabetologist)

'You can see each other smiling and each other's expressions. It just makes for a more pleasant experience.' (Trial coordinator)

Interviewees also commented on the benefits of being able to see the presenter so that the presenter could show them the practicalities of how to label and package samples.

Despite some concern over the ability to build rapport, none of the interviewees felt that having the initiation via videoconferencing rather than face-to-face made a difference to the amount of questions that people asked. In comparison to telephone only initiations, one interviewee commented on the way in which the PowerPoint slides supported participants in asking questions:

'It was nice to be able to chat through the slides as he went through and obviously ask for clarification or even go back on the slides just to bring out another point, so I mean the interactive session was fantastic, I really did like that.' (Trial coordinator)

Two other interviewees also commented on the benefits of being able to follow the PowerPoint slides, in comparison to telephone only initiations:

'It's nice actually to have something visual to look at, to follow as well as you're going… you know, as well as sort of a verbal sort of chat I think, it sort of reinforces it more.' (Research nurse 3)

One interviewee also pointed to the benefit of the chat facility that is part of Adobe Connect, allowing people to ask questions as they thought of them, without having to talk over each other.

Impact on time

Saving time was one of the anticipated benefits for the study team but it was also perceived as a benefit for the participants. We estimate that on average the videoconferencing site initiations took approximately 60 minutes, while a face-to-face initiation would typically last 90 minutes. Two interviewees talked of the benefit of the update taking less time in comparison to face-to-face updates:

'It fits into our day so we're not having to block off whole, you know, afternoons or mornings and cancel stuff, it's just it was beautifully arranged so that it could be done between clinics or lunchtime or whatever.' (Consultant diabetologist)

One interviewee explained how, with a site visit, they feel that they have to make the most of the time that the presenter was there, whereas with the videoconferencing they felt that they could always just speak on the telephone if they wanted to clarify something:

'If somebody has come to visit you, you want to be as thorough, and that sounds awful, and I don't mean it to sound awful because you'll still be thorough when you're still seeing them face-to-face on Adobe Connect, but you know, you don't want to make them feel as though they've wasted their time for a brief 20 minutes, half an hour or hour meeting, you know, you want to make sure that everything is covered. Whereas with Adobe Connect it may not be that much pressure because you can say, well actually can we just have a chat again either on the telephone or whatever, if we've missed something.' (Consultant diabetologist)

However, this shorter duration meant that two of the interviewees felt that it was necessary to do more preparation:

'You need to sit and look at the paperwork because one, it helps when you're going through the presentation to know exactly what it is, you know, you can correlate the two together […] the problem is if you're seeing something completely new in the middle of a presentation you miss one or the other. So actually being able to sort of spend a bit of time with the paperwork and sort of think, right well how is this going to work, and having it sort of maybe in a…I mean I think we had a flowchart, or I put a flowchart together just for my mind as to how we were going to do this and what issues might actually come up from that. And then once we had the [update] we could go back to it and say, right well that's cleared up that point, that's cleared that point, I'm still not sure about this one. And then we could obviously explore that further.' (Research nurse 1)

'When you've got someone in front of you, you tend to have… I suppose because you probably do a bit more small talk, shall I put it that way, and then things suddenly become more… yes, maybe sort of pop into your head. So yes, maybe it does take a bit more thinking about. Because also if you've got someone there you can be sort of thinking and then say, oh by the way I've just remembered that, whereas when you're sort of concentrating, you know, you tend to be more concentrating on your screen rather than sort of thinking around the study.' (Research nurse 3)

However, this issue was not raised by the other interviewees and, when prompted, two of them said that they felt there was no difference in the preparation time required.

Practical challenges

Interviewees were asked how many participants were present for the videoconferencing sessions at their site. Of the two interviewees who had their site

initiation by videoconferencing, one reported that there were three participants in the initiation, while the other interviewee reported that there were two participants. The mean number of participants in the updates across the five sites was three (range 1-5). One interviewee said that they would like a larger screen to better see the presenter, while another interviewee described how using a standard desktop computer meant that the screen was cluttered and everyone was 'huddled around':

'I think the other thing was with it just being an ordinary PC screen he was just a little square […] and when he was demonstrating stuff, I mean okay all he had to do was to show us, you know, the little tubes, but if it was something slightly more intricate than that, that little picture of him… I mean maybe it was me not knowing if I could make him a bit bigger, or whatever, you know, just not knowing my way around the screen. But you know, an ordinary PC screen is, you know, it can be a bit cluttered. But I think if you… I mean if you'd got like plasma screen or something you could connect through to that, then I think, you know, obviously you've got a bit more space.' (Research nurse 1)

However, another interviewee did not mind everyone sitting around the computer, saying that they were used to working that way.

One interviewee had to get their IT department to provide access to Adobe Connect and was only allowed access for a limited time. However, the other four interviewees said that they experienced no technical difficulties and did not require any support from IT staff within their organisation.

Limits of videoconferencing

Two interviewees commented on the fairly simple nature of the study, suggesting that videoconferencing may not be suitable for more complex trials:

'You can't use it for things where there are practical aspects that need to be, you know, you need to show, touch, feel...' (Consultant diabetologist)

'I mean CODIFI was a very straightforward study so I don't think there were huge issues.' (Research nurse 1)

DISCUSSION

We successfully used off-the-shelf web based videoconferencing to deliver site initiations and updates as part of a national multicentre clinical study. Use of videoconferencing enabled initiations to be conducted at geographically distant sites on the same day, expediting the set up phase of the study. The platform enabled streaming of pre-recorded videos, enabling the standardisation of training for the sample acquisition techniques. Use of videoconferencing for conducting site initiations enabled us to maximise the percentage of the study time in which recruitment could take place, with the consequence that the study opened to recruitment early and recruited ahead of schedule. The technology also enabled faster roll out of the subsequent protocol amendment. Survey respondents perceived the videoconferencing technology to have high usability. In the interviews, participants perceived site initiations and updates delivered by videoconferencing as being more interactive and easier to follow than those delivered by teleconference. In comparison to face-to-face site initiations, videoconferencing offers the benefit of taking less time, easily fitting in with the work of staff at the local sites. In terms of the impact on communication, perceptions of this varied according to the technology available at the local site, with participants who had used a webcam having a more

positive attitude. Where this was not the case, there were concerns over the difficulty of building a relationship with the study team when the presenter was unable to see them.

Our experience suggests that videoconferencing is a viable alternative to face-to-face site initiations, at least for uncomplicated studies, even in settings without specific hardware such as webcams and large display screens, and offers benefits over teleconferencing. However, when sites do use a webcam, this may be beneficial, both in terms of building rapport and to enable participants to point to features of forms or equipment in order to seek clarification. Use of videoconferencing makes it feasible to deliver the site initiation over more than one session; the shorter duration of the site initiation when delivered by videoconference, in comparison to face-to-face initiations, may mean that study teams wish to do this, enabling staff at the local site to come back with further questions after the initial presentation. One of our sites used an iPad and the Adobe Connect app to participate in the sessions; the use of the FaceTime video calling service available with iPads and iPhones has been recommended for supporting more informal, spontaneous discussion between remote healthcare professionals (33) but may equally be beneficial for supporting more informal, spontaneous discussion between sites and the study team. More generally, study teams could consider incorporating videoconferencing as one element of building relationships with sites, for example conducting site initiations face-to-face but using videoconferencing for updates. Future trials could compare the impact of conducting site initiations via videoconferencing on site performance as a nested trial within a larger clinical study.

Limitations

This paper describes the use of web based videoconferencing for a fairly simple clinical study, so that the findings may not be generalisable to more complex multicentre clinical trials. The generalisability of our evaluation is also limited by the small number of participants in the evaluation. In particular, participants were self-selecting; all survey respondents reported a reasonably high level of confidence in computer use, so it may be that the evaluation captured those who had a more positive attitude towards the technology. Another limitation is that we were unable to undertake cross-site comparisons of the survey data due to the anonymous nature of the data collected. Finally, this evaluation describes participants' perceptions of the differences between site initiations that are delivered via videoconferencing, teleconferencing, or face-to-face and the study team's perceptions of the success of the initiations in effectively communicating the necessary information. However, previous research has shown that while participants may value videoconferencing, it confers no benefits for communication over teleconferencing (16); we did not attempt to measure differences in duration or the communication differences and the study was not adequately powered to identify statistical differences in the adequacy of data collection procedures (e.g. protocol breaches) or completeness of the CRFs.

CONCLUSIONS

To our knowledge this is the first report of the use of web based videoconferencing to deliver site initiations. Our experience suggests that videoconferencing is a viable alternative to face-to-face site initiations, at least for fairly simple studies, even in settings without specific hardware such as webcams and large display screens, and offers benefits over teleconferencing. We hope that future multicentre clinical studies

will incorporate a formal evaluation of videoconferencing technologies on site performance, including gathering observational data on the differences in communication (including duration) and quantitative data on the impact of method of delivery on participants' understanding of the information communicated and consequences for data collection (e.g. number of protocol breaches and completeness of CRFs). Consideration should also be given to the economic and environmental benefits of reducing the time and travel requirements during set-up, and the subsequent impact on recruitment.

ETHICAL APPROVAL

CODIFI received ethical approval for the clinical study and the present evaluation from the Sheffield National Research Ethics Service (NRES) Committee (Ref: 11/YH/0078) and all sites obtained local approvals prior to commencing recruitment. The study is listed on the United Kingdom Clinical Research Network (UKCRN) portfolio (UKCRN ID: 10440) and International Standard Randomised Controlled Trial Number (ISRCTN) Register (ISRCTN: 52608451).

DECLARATION OF INTEREST

The authors report no conflicts of interest.

REFERENCES

1.   Rosenberg W, Donald A. Evidence based medicine: an approach to clinical problem-solving. BMJ. 1995;310(6987):1122-6.

2.   Friedman L, Furberg C, DeMets D. Multicenter Trials. Fundamentals of Clinical Trials: Springer New York; 2010. p. 427-40.

3.   Kennedy C, Kirwan J, Cook C, Roux P, Stulting A, Murdoch I. Telemedicine techniques can be used to facilitate the conduct of multicentre trials. Journal of Telemedicine and Telecare. 2000 December 1, 2000;6(6):343-7.

4.   Department of Health. Research governance framework for health and social care. 2005.

5.   Cohen J. Identifying and reducing site initiation delays in multinational clinical trials. Global Outsourcing Review. 2006;8(4):38-42.

6.   Lienard JL, Quinaux E, Fabre-Guillevin E, Piedbois P, Jouhaud A, Decoster G, et al. Impact of on-site initiation visits on patient recruitment and data quality in a randomized trial of adjuvant chemotherapy for breast cancer. Clin Trials. 2006;3(5):486-92. PubMed PMID: 17060222.

7.   Embi PJ, Payne PRO. Clinical Research Informatics: Challenges, Opportunities and Definition for an Emerging Domain. Journal of the American Medical Informatics Association. 2009 May 1, 2009;16(3):316-27.

8.   Kahn MG, Weng C. Clinical research informatics: a conceptual perspective. Journal of the American Medical Informatics Association. 2012 June 1, 2012;19(e1):e36-e42.

9.   Nesbitt G, McKenna K, Mays V, Carpenter A, Miller K, Williams M. The Epilepsy Phenome/Genome Project (EPGP) informatics platform. International Journal of Medical Informatics. 2013;82(4):248-59.

10.   Sippel H, Ohmann C. A web-based data collection system for clinical studies using Java. Informatics for Health and Social Care. 1998;23(3):223-9.

11.   Duftschmid G, Gall W, Eigenbauer E, Dorda W. Management of data from clinical trials using the ArchiMed system. Informatics for Health and Social Care. 2002;27(2):85-98.

12.   Fraccaro P, Dentone C, Fenoglio D, Giacomini M. Multicentre clinical trials' data management: a hybrid solution to exploit the strengths of electronic data capture and electronic health records systems. Informatics for Health and Social Care. 2013;38(4):313-29. PubMed PMID: 23957714.

13.   Raptis DA, Mettler T, Fischer MA, Patak M, Lesurtel M, Eshmuminov D, et al. Managing multicentre clinical trials with open source. Informatics for Health and Social Care. 2014;39(2):67-80. PubMed PMID: 24517456.

14.   Nelson EA, Backhouse MR, Bhogal MS, Wright-Hughes A, Lipsky BA, Nixon J, et al. Concordance in diabetic foot ulcer infection. BMJ Open. 2013 January 1, 2013;3(1).

15.   Heath C, Luff P. Disembodied conduct: communication through video in a multi-media office environment. Proceedings of the SIGCHI Conference on Human Factors in Computing Systems; New Orleans, Louisiana, USA. ACM; 1991. p. 99-103.

16.   Sellen AJ. Remote conversations: the effects of mediating talk with technology. Hum-Comput Interact. 1995;10(4):401-44.

17.   Bontempi JB, Runyan C, Heath J. Training by Satellite: Planning and Evaluating a Video Conference for Injury Prevention Practitioners. Journal of Community Health. 1999;24(6):451-66. English.

18.   Demiris G, Edison K, Vijaykumar S. A comparison of communication models of traditional and video-mediated health care delivery. International Journal of Medical Informatics. 2005;74(10):851-6.

19.   Stevenson D, Hutchins M, Smith J. Human-Centred Evaluation for Broadband Tertiary Outpatient Telehealth: A Case Study. International Journal of Human-Computer Interaction. 2010;26(5):506-36.

20.   Groth K, Olin K, Gran O, Permert J. The role of technology in video-mediated consensus meetings. Journal of Telemedicine and Telecare. 2008;14(7):349-53.

21.   Kane B, Luz S. "Do no harm": Fortifying MDT collaboration in changing technological times. International Journal of Medical Informatics. 2013;82(7):613-25.

22.   Kane B, Luz S. Multidisciplinary Medical Team Meetings: An Analysis of Collaborative Working with Special Attention to Timing and Teleconferencing. Computer Supported Cooperative Work (CSCW). 2006;15:501-35.

23.   Li J, Mansfield T, Hansen S, editors. Supporting Enhanced Collaboration in Distributed Multidisciplinary Care Team Meetings. CBMS '08 21st IEEE International Symposium on Computer-Based Medical Systems; 17-19 June 2008.

24.   Li J, Robertson T. Physical space and information space: studies of collaboration in distributed multi-disciplinary medical team meetings. Behaviour & Information Technology. 2011;30(4):443-54.

25.   Li J, Robertson T, Hansen S, Mansfield T, Kjeldskov J. Multidisciplinary medical team meetings: a field study of collaboration in health care. Proceedings of the 20th Australasian Conference on Computer-Human Interaction: Designing for Habitus and Habitat; Cairns, Australia. ACM; 2008. p. 73-80.

26.   Lee KH, Kim JY, Lee K, Cho B, Yang JH, Goh E, et al. Implementation of a videoconferencing system between multiple family medicine departments. Korean journal of family medicine. 2011;32(5):311-6.

27.   Markova T, Roth LM. E-conferencing for delivery of residency didactics. Academic Medicine. 2002;77(7):748-9.

28.   O'Hara K, Kjeldskov J, Paay J. Blended interaction spaces for distributed team collaboration. ACM Trans Comput-Hum Interact. 2011;18(1):1-28.

29.   Storck J, Sproull LEE. Through a Glass Darkly What Do People Learn in Videoconferences? Human Communication Research. 1995;22(2):197-219.

30.   Bangor A, Kortum PT, Miller JT. An Empirical Evaluation of the System Usability Scale. International Journal of Human-Computer Interaction. 2008;24(6):574-94.

31.   Tullis T, Albert B. Measuring the user experience. Burlington, MA: Morgan Kaufmann; 2008.

32.   Miles MB, Huberman AM. Qualitative data analysis: an expanded sourcebook. 2nd ed. Thousand Oaks, California: SAGE Publications; 1994.

33.   Armstrong DG, Giovinco N, Mills JL, Rogers LC. FaceTime for Physicians: Using Real Time Mobile Phone–Based Videoconferencing to Augment Diagnosis and Care in Telemedicine. Eplasty. 2011;11.