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CASE REPORT

USE OF A TABLET TO ENHANCE STANDARDISATION PROCEDURES IN A RANDOMISED TRIAL

Dr Melissa Parker, MD, MSc[1,2]
[1]Paediatric Critical Care Medicine and Paediatric Emergency Medicine, McMaster Children's Hospital, Ontario, Canada, [2]Department of Paediatrics, McMaster University, Ontario, Canada
Corresponding Author: parkermj@mcmaster.ca

Case Report
Standardised operational procedures are important in randomised controlled trials as these help to minimize unwanted sources of variability. Standardisation procedures may be used to orient and train participants as well as research staff with respect to study protocols. In interventional trials involving task performance, use of a standardisation procedure helps ensure that participants have an adequate understanding of the intervention and are able to perform this correctly and consistently prior to formal assessment. This report describes the use of a video displayed on a tablet device to enhance the standardisation procedures of a recently conducted randomised controlled trial. Participants received uniform exposure to instructions. The process was successful and was found to be acceptable.

Journal MTM 1:1:24-26, 2012 doi:10.7309/jmtm.8 www.journalmtm.com

Introduction

Standardisation is an important tool used by investigators to enhance the likelihood of detecting an intervention effect if one in fact exists. Variability may be introduced at the level of the intervention or at the level of outcome assessment.[1,2] In the setting of a randomised controlled trial, standardisation procedures may be used to ensure that the intervention and/or outcome ascertainment is performed consistently and as outlined in the study protocol.[3] Hence, when conducting clinical and non-clinical research, it is important to ensure that study operating procedures are standardised to minimize potential sources of variability apart from the intervention of interest.[4] Variability is not the same as bias, as bias refers to systematic deviation from the "truth"[9]. Data may be accurate but not precise (variability) or precise but inaccurate (bias).[5] Both are problematic from a research perspective: bias risks over or underestimation of treatment effects; while imprecision negatively affects study power and increases the risk of a type 2 error.

The need for clearly defined interventions is reinforced in the most recent CONSORT Guidelines.[6,7] The corollary to this is the requirement for investigators to ensure that these well-defined interventions are applied with rigour and consistency across all participants in the study. This report describes the use of a tablet device as part of study standardisation procedures in a recently conducted randomised controlled trial.

The trial referred to in this article was approved by the Hamilton Health Sciences/Faculty of Health Sciences Research Ethics Board, and is registered at ClinicalTrials.gov (NCT01494116). The study was conducted in accordance with the Tri-council Policy Statement on the ethical conduct for research involving human subjects.[8]

Methods

Forty-eight participants were enrolled in this trial and were tested from October to December 2011. As part of the study protocol, each participant completed the standardisation procedure prior to formal assessment. Testing involved participants performing an intervention on a resuscitation model with the primary

outcome of interest being the amount of time that it took to perform the procedure. As such, it was important to ensure that each participant clearly understood the procedure to be performed and had an opportunity to practice prior to formal testing.

Standardisation procedures can take various forms including printed instructions, explanation using a scripted text, demonstration by a Research Assistant, and/or the requirement to travel to an expert training centre.[3,9] In order to allow timely transmission of both visual and auditory information to participants, a standardisation video was used in this study. The decision to use a video to explain study procedures, including a demonstration of the intervention, facilitated the complete standardisation of the standardisation procedure itself across our study population. Each participant heard the same instructions and saw the same demonstration delivered in the exact same way. Participants then had a brief opportunity to practice in order to reduce variability attributable to the training or learning phase.

The standardisation video was created with use of a Canon VIXIA HF R20 HD camcorder. Video data was then transferred to an Apple iMac computer (model iMac12.2) for review and video editing using iMovie '11. Once the standardisation video was finalized, it was then uploaded to iTunes 10 to enable transfer onto an iPad 2 tablet device, trademark of Apple Inc. (32 GB with Wi-Fi, Apple model A1395). As is required for all data files, transfer of the video file from iTunes onto the iPad was achieved through synchronization of the iPad with the iMac computer. The standardisation video could then be easily launched from the iPad using the touch pad screen, which also served as the video display. (Refer to Figure 1).

The standardisation video used in this study was 3 minutes, 20 seconds in length. The video included an explanation of the study premise, an orientation to testing equipment and the model, and a demonstration of the procedure to be performed. A single Research Assistant was responsible for coordinating participant testing, including administering the standardisation procedure through use of the iPad. Minimal training was needed to orient the Research Assistant to the iPad, which she had not used previously.

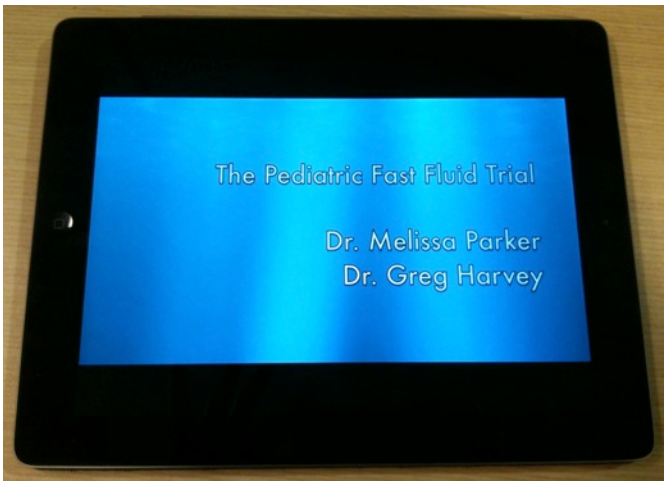

Figure 1: Apple iPad with trial standardisation video displayed

Discussion

The process results in each participant viewing the same instructions and demonstrations in a consistent manner. The Research Assistant did not encounter any technical difficulties using the iPad during the course of the study and in fact spoke highly of its ease of portability and ease of use. Many of the participants who participated in this study also offered spontaneous positive comments regarding their experience viewing the standardisation video using the iPad.

Use of a tablet device as part of study standardisation procedures is not without its potential limitations. To achieve the intended purpose, the Principal Investigator must ensure that standardisation videos are clear and accurately reflect the study protocol. Specific instructions should be provided to any staff tasked with creating a standardisation video. The video narrator should use simple language and avoid the use of any unnecessary technical terms. Demonstrations should be filmed in a well-lit environment, and walk the viewer through the procedure or technique in question in a stepwise manner. Researchers may opt to show the standardisation video to individuals not participating in the study to ensure clarity prior to use with study participants. Additionally, while an iPad was used in this study, alternative tablet devices could be used for similar purposes. These devices may make it easier to transfer video to the tablet.

Conclusion

This report describes the successful use of an iPad to administer a standardisation procedure in the setting of a randomised controlled trial. It is easy to envision how tablets could be used to facilitate other aspects of standardisation in the context of research studies, including training modules for research assistants and laboratory technicians.

Acknowledgements

The author would like to acknowledge the assistance of Ms. Asmaa Manan and Dr. Greg Harvey who assisted in creating the standardisation video referred to in this article. Ms. Manan also served as the Research Assistant and Dr. Harvey served as a Co-investigator in the trial in which this procedure was used.

Both Ms. Manan and Dr. Harvey have consented to being acknowledged in this article

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