Published in final edited form as:

Contemp Clin Trials. 2011 July ; 32(4): 544–546. doi:10.1016/j.cct.2011.03.005.

Data Acquisition for a Patient-directed Intervention Protocol in the Dynamic Intensive Care Unit Setting

Linda Chlan, PhD, RN,

School of Nursing, University of Minnesota, 5-160 Weaver-Densford Hall, 308 Harvard St. SE, Minneapolis, MN 55455, Phone: 612-624-6658, FAX: 612-625-7180

Robert P. Patterson, PhD, and

University of Minnesota, Department of Physical Medicine and Rehabilitation and the Institute for Engineering in Medicine, 420 Delaware St., MMC 297, Minneapolis MN 55455, patte001@umn.edu

Annie Heiderscheit, PhD, MT-BC, FAMI, LAMFT

Center for Spirituality and Healing, University of Minnesota, MMC 505, Mayo Memorial Building, 420 Delaware Street S. E., Minneapolis, MN 55455, heide007@umn.edu, Phone: 612-624-7669, FAX: 612-626-3280

Abstract

Methods to easily, accurately, and efficiently obtain data in an ICU-based clinical trial can be challenging in this high-tech setting. Patient medical status and the dynamic nature of this clinical setting further complicates data collection. The purpose of this paper is to describe the modifications of commercially available headphones and the application of a data logging device to capture frequency and length of protocol use (music listening or headphones only for noise cancellation) without burdening participants or busy ICU nurses. With the automatic capture of protocol use by research participants, there have been no instances of lost data for this clinical trial.

Keywords

intensive care unit; clinical trial; data collection

Introduction

Instituting a clinical trial protocol in any healthcare setting can be a challenge. In the intensive care unit (ICU), this challenge is compounded by many factors including the ever-changing and dynamic nature of the environment and the fluctuating status of patients' themselves. ICU nurses cannot be burdened with research protocols or any associated data collection as their attention needs to be fully directed towards the care of critically ill patients. Investigators need to carefully design research protocols to minimize any burden on participants and on nurses caring for these patients in order to successfully conduct a clinical

© 2011 Elsevier Inc. All rights reserved.

Corresponding Author: chlan001@umn.edu.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

trial in this setting. Furthermore, data must be obtained reliably, accurately, and efficiently when research participants themselves have significant energy limitations. The purpose of this paper is to present details on a headphones system that was devised for this clinical trial to efficiently and effortlessly capture equipment use and listening time in a sample of critically ill patients receiving mechanical ventilatory support. Modifications to commercially available headphones are described, as is the application of a commercially available data logging device to this headphones system to capture use of the intervention protocol by our research participants.

Material and methods

Description of the ICU-based Clinical Trial

The overall aim of our randomized clinical trial is to determine if individually preferred, relaxing music can reduce anxiety over the course of mechanical ventilatory support in critically ill ICU patients. Secondary aims are to determine if relaxing music leads to shorter time receiving mechanical ventilatory support, shorter length of ICU stay, and if music reduces stress. This study has been approved by the parent Human Subjects' Committee (University of Minnesota) and all of the participating sites' human subjects' committees.

Mechanically ventilated patients are recruited from 5 medical centers in the Minneapolis-St. Paul urban area, which includes a total of 12 individual ICUs. Patients are approached who are consistently following commands, participating in their daily care, and can provide informed consent. Subjects are randomly assigned to one of three conditions: 1) experimental group of patient-directed music (PDM) listening whereby they listen to music specially assembled by a music therapist that compliments their music preferences whenever they like for as long as they like, 2) active control condition of noise-canceling headphones whereby subjects wear headphones to block out ICU noise whenever desired, and 3) control group of usual ICU care for the respective unit.

Patients remain in the study as long as they are receiving mechanical ventilatory support in the ICU, for up to 30 days. Anxiety is assessed daily with two paper and pencil instruments; a 6-item shortened version of the Spielberger State Anxiety Inventory [1] and a 100-mm visual analog scale-anxiety. Urine is collected daily for cortisol as an integrative measure of stress.

Implementation of the PDM and Headphones Protocol—After randomization to the PDM group, a board certified music therapist meets with subjects to assess their music preferences. A music assessment tool (MAT) has been developed to assist in gathering the information on music preferences [2]. Mechanically ventilated patients face many challenges in their efforts to communicate. Alternate methods of communication are used, such as note writing, asking yes/no questions, or speaking with family members.

After music preferences have been determined, the music therapist compiles the desired selections onto CDs. These CDs are then delivered to the participant's bedside. The music therapist reviews the music choices with the participant with reminders to listen to the music whenever and for as long as desired. In addition, the music therapist also makes specific recommendations as to when participants may find the music helpful, such as to promote restful sleep. The music therapist meets with each participant daily while on protocol, which allows for ongoing assessment and refinement of music selections.

Music CDs are played on a portable CD/MP3 player. The output from the player is connected to a noise canceling headphone (Maxell model HP/NPII). Subjects randomized to

the headphones only active control condition use the same headphones as the PDM group. They are encouraged to wear the headphones to block out noise when quiet is desired.

Given the illness severity of participants, cooperation among nursing staff is essential with protocol implementation. Participants may be weak and fatigued, thus nursing staff may be asked to assist with headphone application and removal. Participants cannot be asked to self-monitor equipment use given their medical condition and low energy states. Methods for self-initiation of music listening or headphones application must be simple for participants to manage. However, data capturing frequency and length of equipment usage must be obtained efficiently and accurately without burdening participants or busy ICU nursing staff. Methods to automatically capture equipment usage were needed for this study, which are described below.

Methods to Efficiently Track Patient-Directed Interventions Use

Headphones Modification and Application of a Data logging device—

Headphones required alteration in order to efficiently track each time PDM or headphones were used. This work was performed under the direction of the study biomedical engineer (RP). On the hard bracket that contained the left earpiece, three microswitches were placed that closed when the headphone unit was placed on the head. Two of the switches were used to connect the electrical sound signal to the right and left headphone. A third switch was used to control a small HOBO® data logging computer (Onset Computer Corp., Pocasset MA, model HOBO® U9). The HOBO® computer stores the data creating date and clock time stamps for each switch closure and opening. Therefore, the data indicates when the headphone units are used to listen to music or worn without music to obtain noise cancellation. The resolution of the listening time period is one second, which means the status of the switch state is sampled by the device every second. The time of day clock of the data logger's accuracy is ± 1 minute. Additional details on the U9 data logger can be found on the manufacturer's web site (www.onsetcomp.com).

Data Shuttle—To prevent loss of any equipment usage data while participants are enrolled on protocol, we use the HOBO U-Shuttle®. The shuttle allows the transfer of data from many individual HOBO® U9 data loggers to be downloaded to a small, palm-sized device. This shuttle allow us to collect and transfer the data from repeated participant equipment use, and for collecting data from more than one subject in remote locations. The data from the HOBO U-Shuttle® is then transported to the central research office where all of the data can be downloaded from the shuttle into the main computer.

The output from the HOBO® shuttle computer is read using the HOBOWare program (Onset Computer Corporation). The HOBOWare software gives the time of each switch closure, but does not give the time intervals or the total time period of use. Therefore a program was written using PowerBASIC (PowerBASIC Inc., Venice FL), which takes the output file from the HOBOWare program and gives the time intervals of headphone use and also creates data files from repeated uses in a format that can be easily analyzed using EXCEL (Microsoft Corp., Redmond WA).

Testing Equipment Integrity—To ensure that the headphone system is accurately logging use and capturing data, a standard quality check is performed each day at the research site. The data logger is activated via the headphones switch for a pre-determined amount of time, two minutes, while the data logger is visually observed to ensure active logging. When data are down-loaded from the shuttle, this 'test' appears in the read-out verifying the unit is working as intended. Research nurses carry extra headphone sets with data loggers in the event that there is any question that the system is not logging

appropriately. Units are replaced as needed. Any questionable units are tested in the research office and returned to circulation only after resolution. The usual reason for the U9 to not log appropriately is that the headphone bracket switch unit needs to be adjusted.

Results, Discussion, and Conclusions

The purpose of this paper is to detail one headphones system that was adapted to meet the needs for obtaining data from mechanically ventilated patients participating in a clinical trial. Using this system with commercially available products has resulted in no loss of study equipment usage data over the course of this trial. We have found the U9's and shuttles to be extremely reliable in concert with our daily equipment integrity checks. We have had to make repairs to the switch brackets on numerous headphones units, particularly for those participants that frequently use the equipment.

One limitation is that we do not ask participants or nursing staff to manually track equipment usage, which would be burdensome and inaccurate in this dynamic research setting. We are not able to independently verify the obtained data as actual listening or wear time. We cannot discern if indeed the participant was actually listening to music or wearing the noise-canceling headphones. However, given our daily quality checks and interactions with participants, we are confident that participants are indeed using the equipment.

The headphones system adapted for this trial has worked well. We are confident that other researchers can develop similar systems to capture necessary data for their clinical trials.

References

- [1]. Chlan L, Savik K, Weinert C. Development of a shortened state anxiety scale for patients receiving mechanical ventilatory support. *J Nurs Measur*. 2004; 11:283–293.
- [2]. Chlan L, Heiderscheid A. A tool for music preference assessment with critically ill patients receiving mechanical ventilatory support. *Music Therapy Perspectives*. 2009; 27:42–47.

Web References

3. Onset Computer Corporation. www.onsetcomp.com