

Merging technology and clinical research for optimized post-surgical rehabilitation of lung cancer patients

Amy J. Hoffman¹, Ruth Ann Brintnall², Julie Cooper²

¹College of Nursing, Michigan State University, East Lansing, Michigan 48824-1315, USA; ²Kirkhof College of Nursing, Grand Valley State University, Grand Rapids, Michigan 49503, USA

Contributions: (I) Conception and design: AJ Hoffman, RA Brintnall; (II) Administrative Support: All authors; (III) Provision of study materials or patients: All authors; (IV) Collection and assembly of data: All authors; (V) Data analysis and interpretation: AJ Hoffman, RA Brintnall; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Amy J. Hoffman, MSN, PhD, RN. Associate Professor, Michigan State University, College of Nursing, Office C246 Bott Building for Nursing Education and Research, 1355 Bogue Street, East Lansing, MI 48824-1317, USA. Email: amy.hoffman@ht.msu.edu.

Background: The 21st century has ushered in an age of wireless communication and technological breakthroughs providing researchers with opportunities and challenges as they incorporate this technology into their research. This paper presents the challenges our team encountered introducing new technologies and how they were overcome for an intervention for post-thoracotomy non-small cell lung cancer (NSCLC) patients.

Methods: Our intervention incorporated the Nintendo Wii Fit Plus virtual-reality walking and balance exercise into a home-based rehabilitation program. The intervention is novel and innovative in that the intervention provides light-intensity exercise post-thoracotomy for NSCLC patients immediately after return to home from the hospital. The intervention overcomes the barriers of conventional exercise programs that require travel, conventional exercise equipment, and begin months after surgery.

Results: When translating new technology to research, researchers need to consider a number of factors that need to be addressed. Institutional Review Boards may need further explanation as to why the technology is safe, potential participants may need to have unfounded concerns explained before enrolling, and the research team needs a plan for introducing the technology to participants with a vast range of skill sets and environments in which they will be using technology. In our study, we addressed each of these factors using varying approaches as we translated how the Wii would be used in a home-based exercise intervention by a highly vulnerable, post-thoracotomy NSCLC population.

Conclusions: While technology brings with it multiple barriers for successful implementation, our team showed that with proper planning and teamwork, researchers can navigate these issues bringing the full benefit of technology to even the most vulnerable of patient populations.

Keywords: Exercise; fatigue; lung cancer; rehabilitation; technology

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Introduction

The 21st century has brought significant technological advances providing researchers with a plethora of avenues to incorporate state-of-the-art interventions into clinical research (1). The influence and evolution of the internet and wireless communication provide technology for intervention development that mitigates barriers that

seemed previously insurmountable. Likewise, improvements in health care technology have grown exponentially in the 21st century changing the landscape of clinical research and bringing with it significant improvements and challenges to how research is conducted. New methods of communication, new measurement capabilities, and a host of accumulating evidence have helped to shape the world of

research we live in today. Consistent with the general public where there are those driven to have the latest gadgets and those that stay with tried and true products, researchers can be early adopters incorporating new technology into their research or late adopters who wait until new technologies and methods have been tested and established before adopting them. Likewise, researchers need to accept that study participants will also fall into these categories and adjust their study approach to account for both categories of participants. Flexibility becomes important especially when patients are under stress facing life-limiting illness where learning new technology becomes another daunting task to add to patient stress. As such, researchers have to understand that while technology can remove obstacles, it can create others and may not be readily embraced by participants. The objective of this paper is to provide insight into some of the challenges we experienced conducting a technology based intervention for the benefit of post-surgical non-small cell lung cancer (NSCLC) patients, one of the most vulnerable populations (2).

Methods

Despite health care advances, post-surgical NSCLC patients continue to be one of the most vulnerable and underserved cancer populations (3,4). Mounting evidence reveals that the NSCLC population frequently presents with multiple comorbid conditions and complex treatment plans making them especially vulnerable during the transition from hospital to home (5,6). In a study of 888 individuals with differing cancer diagnoses from initial diagnosis to two years after diagnosis, having lung cancer was found to be a strong independent predictor of reporting more unmet needs as compared to all other cancer diagnoses combined (7). Research to date on individuals with NSCLC identifies the most common unmet supportive care needs as managing fatigue and physical deterioration, performing activities of daily living, and receiving support to exercise (8-10). Research reports that greater levels of supportive care needs are associated with greater symptom distress and declining physical function (3). Fatigue is a prevalent, severe, and debilitating cancer symptom particularly dominant in individuals with lung cancer, and it persists after diagnosis and treatment (11-13). Likewise, fatigue is widespread and consistently ranked as the most common and unmanaged symptom in individuals with cancer leading to lower physical functioning (14). With this in mind, our clinical research team designed a post-surgical exercise intervention

using the Nintendo Wii that could be performed in the patient's home after discharge (2). Our research addresses the National Cancer Institute, National Institutes of Health, recommendations for high-priority research focused on overcoming barriers to implementation and strategies to increase uptake and effect size of interventions such as exercise to address cancer-related fatigue management (15). This intervention is novel and practical in that it is home-based, initiated upon return from the hospital and uses virtual reality technology to provide an entertaining and convenient means to exercise post-surgical NSCLC patients to address difficult barriers frequently described in the literature (16,17). This is significant since a notable barrier to cancer-related fatigue management is there are no formal guidelines for rehabilitative exercise for the post-thoracotomy NSCLC population (18). Additional known barriers to rehabilitative exercise include the frequent presence of co-morbid conditions with associated symptoms, changes in functional status and quality of life after surgery, and the burden of living with a life-limiting illness. These barriers are beyond those reported by healthy individuals such as time constraints, travel and weather issues, and perceiving exercise as boring work (19). Evidence demonstrates that exercise is the most effective means to target cancer-related fatigue, fatigue due to cancer and its treatment (20), and guard against its onset (21). While few in number, previous exercise interventions for this population were conducted in hospitals using conventional means of exercise such as treadmills (22-24). Further, previous exercise research interventions are started weeks to months after returning home from the hospital post-thoracotomy for lung cancer. However, when conducting our study (2), we learned of previously unforeseen obstacles to include achieving multiple institutional review board (IRB) approvals, recruitment, participant use of unfamiliar technology, and data collection.

Results

Addressing technology innovations with institutional review board members

The first obstacle our team had to overcome was accommodating issues raised by the IRBs regarding the implementation of our intervention on this highly vulnerable post-surgical lung cancer population. We found the most critical IRB concern was relative to the safety of the new technology in our patient population. Select

IRB members stated that the intervention was “too risky” requiring the use of the Wii balance board which is a wide, stable platform that is elevated two inches above the floor that IRB members were worried participants could fall and hurt them. In order to overcome this criticism, we met face-to-face with the IRB members to answer questions and visually demonstrate stepping on to the two-inch platform. The personal demonstration worked well as members that read about the “risky” balance board were now laughing, stating “that’s it?” Next, some IRB members were concerned that an in-home exercise and balance intervention was unsafe in a post-surgical population and as a result members wanted to require a spotter for every exercise session. Fortunately, an influential, elderly community board member fought for our intervention stating that a spotter was too intrusive for families; he stood up and said, “*I’m tired of you young folks telling us what we can and can’t do. We will never have a solution to this problem if we don’t start somewhere.*” In fact, when arguing that the two-inch platform concern was unwarranted, this board member stated “*What do you want to do, bubble wrap us?*” This was a case where technology provided an entertaining means of rehabilitation with a convenient method of delivery but some IRB board members were not comfortable with the innovative method of delivery. Likewise, evidence from evolving brain science was presented to the IRB members showing when patients are transported to varying, enjoyable environments they become immersed in the new environment (25,26). This immersion in a pleasant environment allows patients to overcome the unpleasant barrier of exercising by introducing a proactive attention control strategy to self-attract pleasant thoughts, relieving the unpleasantness of unwanted symptoms [(27), p147]. In our case, our research goal was to provide prevention and elimination of one of the most prevalent and severe symptoms, cancer-related fatigue. Moreover, we presented evidence that deconditioning and falls, a major public health problem in older adults, were avoided when people participated in exercise (28,29). Similar to the experiences of our team, researchers need to understand that when they introduce an innovative use of a new technology, the IRB may not be as enthusiastic and may impose restrictions resulting in a slower introduction of new technology and realization of the intervention’s value. In our case, the one influential IRB member provided our team with the opportunity to implement our intervention without limitation. Researchers need to anticipate that face-to-face meetings with the IRB demonstrating the proposed

technology may be necessary to address unwarranted fear regarding the use of new technology. Fortunately, our face-to-face meeting with the IRB provided our team with the IRB consent needed with no restrictions to conduct our study.

Technology innovations and recruiting

Reports estimate that only 2% to 5% of newly diagnosed adult cancer patients enroll in clinical trials in the United States (30). We understood our overall challenge addressing the known barriers to recruitment to do a better job of educating our potential participants about the benefits and safety of clinical research to produce advances in rehabilitation; and to make it easier for our oncology community to provide their patients with opportunities to enroll onto our clinical study (31). Key barriers relevant to our study included older patients (32), patients commuting from rural areas (33), having a target population with a new diagnosis of lung cancer (32), and participating in surgical oncology research (34). However, recruiting participants to a study using new technology needs special consideration as participants need to be provided with necessary information in a short period of time in order to make an informed decision on whether or not to join the study. In our study, we also had to consider the age range of our participants and the potential lack of knowledge they had relative to the technology they would be using in our intervention. The average age of individuals with lung cancer at diagnosis is 70 years (35). Since the Nintendo Wii is video gaming technology used primarily by children and young adults, we had to consider that many of our potential participants would not know what it was so we would have to spend some time teaching the technology and how participants would be using it to rehabilitate. Likewise, we anticipated that those that were not familiar with the Wii may not like the idea of having the Wii connected to their television and the perception the Wii may break or affect their television’s performance. What we found is that most of our participants were not familiar with the Wii as we expected, and those that were familiar with it knew of it from their grandchildren. We also found that some potential participants were wary of connecting anything to their television so our anticipation of these issues helped our recruiters talk through these concerns so they did not have a negative impact on recruiting. In general, we found the technology proved to help in our recruitment process as potential participants embraced the notion of

using a video game in their rehabilitation. However, one recruitment site over-compensated for the concern that potential participants would need more time to understand the technology so they insisted participants go home and read more about it before enrolling. Potential participants became irritated with this as many wanted to enroll when they were on-site as many lived over an hour away from the recruitment site and many of these participants declined to enroll as they did not want to drive back in to do so. This recruitment method was changed allowing participants to consent to participate in the study as they wished, greatly improving our recruitment rates. In this case, the site's unnecessary concern that participants must have extra time to understand the technology before they could make an informed decision ended up denying potential participants participation.

Researchers need to consider how technology will be perceived by their patient population. Researchers need to anticipate negative perceptions regarding the technology they plan to use so they can neutralize concerns during recruitment while emphasizing the positive aspects associated with the proposed technology. Likewise, any unforeseen or unwarranted concerns raised by potential participants during the initial recruitment phase need to be addressed by the research team immediately so these concerns can be addressed. Active participation by the principal investigator during the early stage of recruitment can help with the assessment of strengths, weaknesses and opportunities so that adjustments can be made quickly. Once participants were recruited, our team needed to ensure a smooth implementation of the intervention.

Initial application of technology in the home

Implementing new technology in a research study has its own set of challenges when applied to a broad participant population. Selecting the technology that best fits the target population with varied skill sets and resources can be challenging. In implementing our study, we wanted to take advantage of the latest technology in virtual reality walking and balance exercise that would be most appropriate for our target patient population. We selected the Nintendo Wii Fit Plus for its ease of use and its variety of balance exercises. Since our intervention is a home-based intervention we spent time trying to anticipate what we might encounter while initiating this intervention into a variety of homes. From a technology standpoint we reviewed potential television connectivity issues with the Wii before starting

the study. Each in-home nurse learned how to setup the Wii and educate participants on its exercise use during the first in-home visit. Expert consultation by nurses with face-to-face contact is documented as a motivator to promote exercise (21,36). Likewise, we had a technology assistant on call to assist in setting up the Wii just in case there were any connectivity issues we had not considered (36). This was important as participants were concerned about our research staff connecting the Wii to their television. We were concerned that if we had issues connecting the Wii, participants could elect to drop out of the study. Further, we asked participants if they had any friends or family members that were familiar with the Wii so they could help if they were available [(27), p416]. For our study, planning ahead was very beneficial in connecting the Wii as we faced many of the issues we planned for as well as multiple issues that we had not expected. Our team shared their various experiences and how they overcame connectivity challenges during planned communication sessions. Soon we were able to address nearly all of the possible connectivity scenarios we would face. However, there was one case we were not able to overcome where a participant required that we use a television built in the 1970s and this television did not have any external connectivity that could be used with the Wii. We learned that our concerns regarding connectivity were valid and that during the initiation phase our plan for a nurse with technical support worked well. We learned a valuable lesson from this study related to technology—that is, anticipating and incorporating technology across a broad set of use case scenarios must be considered.

Ensuring measuring technology

With technology ever expanding, measurement capabilities have also expanded. However, the latest in technology is not always the best fit when considering the needs of the study and the capability of participants [(27), p299-302]. Once we had selected the Wii, we needed to select a method for measuring daily activity. In this case, we selected pedometers as the method for measuring daily activity. As such, our team selected a pedometer that was simple and easy to use and demonstrated internal consistency and reliability. In our study, our target lung cancer population had a mean age of 65 years with multiple co-morbid conditions to include arthritis. While the majority of pedometers on the market performed many functions, we were concerned that the multiple functions would create confusion to the participants interfering with their ability to record their

daily number of steps. In this case, the latest technology with its extra functionality was not our best choice. We needed to keep the pedometer simple to eliminate the possibility that participants would record the wrong numbers or get frustrated and not enter any pedometer data. Even with the choice of the simplified pedometer, we found that some participants had issues using the simplest of pedometers. While participants were instructed to fasten their pedometer on their belt, some participants decided to use their own technique in wearing the pedometer [(27), p7]. One participant decided to attach their pedometer to their shoe, another on their glasses, and a third on a pocket in their robe—all of which could give misleading results. We learned the value of regularly scheduled in-home visits with follow-up phone calls to provide patient education to ensure intervention fidelity relative to the use of technology (36). Our team learned that even with teaching participants how to use technology, participants will take it upon themselves to implement technology in their own way. Hence, researchers need to anticipate that participants will come up with their own way to implement technology and be vigilant for this so that additional training or alternative methodologies can be invoked to ensure the correct use of technology. While researchers need to be concerned with the correct use of technology, they also need to be concerned about the environment in which the technology will be used.

Environmental considerations

One of the significant advantages that the latest technology has brought is convenience and flexibility. The internet, cell phones, wireless devices, and portable communication devices all provide or allow for the transmission of data nearly anywhere at any time. This brings a significant level of intervention flexibility to researchers not available in the past. Participants no longer have to travel to intervention sites to participate in a study making it easier for them to participate and easier for researchers to recruit participants to their study (33). However, this flexibility can also make it difficult for the researcher to control the study environment. In our study, the technology we used allowed us to conduct our intervention research in participants' homes. This flexibility helped remove the typical barriers to exercise and enhanced our recruiting efforts (37). However, this flexibility also meant that our intervention would be incorporated in multiple participants' homes. In addition to learning about the variety of television sets and connectivity

cables, we learned to place the Wii in floor space that would not compromise movement between rooms or patient safety. We also needed to incorporate the Wii's password capability so that friends or family members that decided to use the Wii would not affect the data being collected for the participant [(27), p416]. Further, since our data collection included the use of paper logbooks as a motivator to exercise (36), we learned that these varied environments also included cats that enjoyed shredding our paper logbooks so we supplied plastic page protectors to adjust for this environmental surprise. Likewise, we used pets to our advantage since the Wii allowed for creation of dogs and cats we showed participants how they could create and name their pet in their virtual environment making their exercise experience more enjoyable [(27), p408]. We learned this in one of our home visits when the nurse told the participant "now let's go for a walk!" and the family pet ran to the nurse. Researchers need to do their best to anticipate the issues they will encounter in incorporating technology in 21st century intervention studies and be ready to address them with workable solutions. Further, since it is nearly impossible to anticipate all the different environmental scenarios that will need to be addressed, researchers need to monitor the various environments early on in the study so lessons learned can be applied immediately when similar environmental issues arise.

Conclusions

The use of rapidly advancing technology brings with it a multitude of opportunities for researchers and research participants to expand our knowledge base through interventions that were never possible to implement in the past. While the 21st century provides significant opportunities to conduct research in ways never imagined through the use of technology, these new opportunities also bring with them a number of considerations that need to be addressed in order to use the technology successfully. In order to tap into the full potential technology can bring to enhance clinical outcomes, researchers need to anticipate and have answers for IRBs that will scrutinize technology for concerns including participant safety. Likewise, researchers need to consider and address potential issues their population may have in understanding the technology during recruiting and also when using the technology. Further, researchers need to consider the breadth of capability their participant population can support and ensure that the technology they choose can be

used successfully by their least capable participants. Also, researchers need to consider the environment in which the technology will be used and consider the possible scenarios that need to be accommodated so the technology can be used successfully. In implementing our study, we learned that the ramifications of incorporating new technology need to be considered during each phase of the research study. We also learned that as much time as we spent going over potential issues of using our technology in our intervention study, we always experienced challenges we never anticipated. The key to the successful implementation of our study was the vigilance of our research team to identify unanticipated issues early on in the study and developing corresponding solutions that we used throughout the study. While incorporating new technology was challenging, it also was rewarding as we saw participants who would have never been able to participate in a traditional site-based exercise program succeed in our home-based exercise intervention providing a feasible means for post-surgical lung cancer patients to treat their cancer-related fatigue.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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