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Methodological Challenges Encountered in a Study of the Impact of Animal-assisted Intervention in Pediatric Heart Transplant Patients

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ABSTRACT

Purpose: The purpose of this pilot study was to examine the impact of animal-assisted intervention (AAI) on ambulation, physiologic stability, patient satisfaction, and perceived benefit in hospitalized pediatric heart transplant patients.

Design and methods: This pilot study used a two-period, two-sequence cross-over design. Using a convenience sample of heart transplant patients between the ages six and nineteen, each subject participated in one AAI and one non-AAI study session over one week. All study sessions started with an aspect of walking.

Results: Three males and two females participated. Average age was 15 years. Subjects walked on average 1906 ft during the AAI session as compared to 1933 ft in the non-AAI session. Subjects spent a longer time (17 min) walking in the AAI session as compared to the non-AAI session (15 min). Blood pressure and respiratory rates remained stable. All subjects reported they liked working with the dog. Eighty percent of subjects actively engaged in physical contact and communication with the dog. No safety-related adverse events were reported.

Conclusions: AAI may assist adolescent heart transplant patients to be more motivated to participate in therapeutic ambulation when walking with a dog. Further studies are needed to identify successful recruitment strategies in this highly vulnerable patient population.

Practice implications: Many clinical challenges exist in implementing AAI research in the pediatric heart transplant population. A conceptual model is introduced to better understand the methodological challenges of conducting AAI research in the hospital setting. Key components include research, organizational, AAI, subject and time factors.

Pediatric heart failure and transplant

The prevalence of congenital heart disease (CHD) at birth ranges from 6 to 13 per 1000 live births (Altman, 2018). Thirty years ago, most neonates and infants with moderate to severe CHD did not live past infancy. Advances in cardiac medicine and intensive pediatric care technology along with improved surgical approaches and techniques have resulted in an increasing number of survivors living into adulthood. The number of adult survivors living with CHD was estimated to be 787,800 in 2002, increasing to 2.4 million adult survivors in 2010 (Gilboa et al., 2016; Hoffman, Kaplan, & Liberthson, 2004; van der Bom et al., 2011).

The International Society for Heart and Lung Transplantation (2018) reported that 61 pediatric heart transplants were performed in North America in 2016 and 128 transplants were performed worldwide. Complex CHD lesions, despite corrective or palliative surgery, usually have a common clinical course that leads to chronic end-stage heart failure, poor quality of life and eventually death. Rossano et al. (2012) reported the incidence of pediatric heart failure as 0.97 to 7.4 per 100,000, with approximately 11,000 to 14,000 children being hospitalized for heart failure management annually. Medical management options for end-stage pediatric heart failure are limited and usually includes destination therapies such as anti-congestive medications and/or heart transplantation. While pediatric heart transplantation offers long-term survival for pediatric patients with end-stage heart failure, the procedure is

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associated with its own specialized set of complications secondary to immunosuppression and chronic end organ dysfunction (Das, 2018).

Managing and caring for patients after a heart transplant procedure can be challenging for the multi-disciplinary intensive care unit and transplant teams. Postoperatively, heart transplant recipients are recovering from a long operative procedure after enduring many months to years of clinical debilitation due to end-stage chronic heart failure. Their clinical condition is both directly and indirectly dependent on their clinical condition prior to the surgical procedure. While the ideal surgical candidate is one who has controlled heart failure and has undergone cardiac rehabilitation during the wait-listed period with adequate nutritional intake, these ideal patients are few and far between. The typical recipient is undergoing operative recovery, cardiac rehabilitation, as well as dealing with the new challenges of immunosuppression and graft function. Patient care goals in the postoperative period are focused on recovery and preventing any issues and complications associated with increased morbidity and mortality such as infection and graft rejection. Recovery time after a pediatric heart transplant is patient dependent, and it can be weeks to months before the patient is discharged to the home setting.

Animal-assisted intervention (AAI)

Complementary therapies such as AAI have shown promise in: 1) normalizing the hospital experience for patients and their families; 2) motivating active participation among children in their treatment; 3) providing helpful distraction from pain, worry, anxiety, and unhappiness; and, 4) lessening the distress experience during medical examinations and treatments (McFarland, Mariani, & the American Humane Association, 2012; Wu, Niedra, Pendergast, & McCrindle, 2002). AAI is defined by Pet Partners (2017) as "goal oriented and structured interventions that intentionally incorporate animals in health, education, and human service for the purpose of therapeutic gains and improved health and wellness" (page 10). The use of AAI has been well documented as an adjunct therapy that improves mood, reduces loneliness, decreases pain perception, and encourages movement. AAI is found to improve coping with hospitalization by reducing anxiety, agitation and fear of painful medical procedures (Braun, Stangler, Narveson, & Pettingell, 2009). Anxiety and stress reduction are particularly important in pediatric populations as children may not fully understand the reason for their hospitalization or be able to put their feelings into words (Snipelisky & Burton, 2014).

Maintaining physical endurance is a primary therapeutic goal in the care of pediatric heart transplant patients. While much anecdotal and pilot study research exists surrounding the benefits of AAI in hospitalized adult patients, no studies were located that examined the effect of AAI in pediatric heart transplant patients. In a study examining AAI in hospitalized adults with heart failure, Cole, Gawlinski, Steers, and Kotlerman (2007) demonstrated improved cardiopulmonary measures and decreased anxiety with AAI compared to a visit from a hospital volunteer or standard therapy group. In another study examining AAI in hospitalized adults with heart failure, Abate, Zucconi, and Boxer (2011) demonstrated that subjects were able to walk 120 steps farther when using a therapy dog than a historical control group without a dog.

Novotny, Deibner, and Herrmann (2015) conducted a mixed methods study examining the feasibility of using AAI to promote ambulation in adult cardiac patients. Study findings indicated that AAI was safe, not time or resource intensive for staff, and was overall well supported by healthcare providers. Challenges of AAI included patient recruitment difficulties, insufficient numbers and availability of dog/handler teams for daily use, and patient scheduling difficulties (Novotny et al., 2015).

Purpose

The purpose of this pilot study was to examine the impact of AAI on ambulation, physiologic stability, patient satisfaction, and perceived benefit in pediatric patients hospitalized in a cardiovascular intensive care unit (CVICU) within a large academic childrens hospital.

Methods

This pilot study used a two-period, two-sequence cross-over design. The cross-over design was used to reduce the influence of confounding variables since each subject served as his/her own control.

Setting and sample

The Heart Center at Arkansas Children's Hospital is a 30-bed pediatric intensive care unit that cares for patients with congenital or acquired heart disease. The pediatric cardiovascular surgical program focuses on corrective or palliative procedures including cardiac transplantation. Advanced cardiac support in the form of extracorporeal membrane oxygenation (ECMO) or ventricular assist devices such as the Berlin Heart EXCOR™, HeartWare™, or the Syncardia Total Artificial Heart™ are available for children with end-stage heart failure as a bridge to cardiac transplantation.

Eligible subjects included pediatric patients ages 6 to 19 years of age admitted to the pediatric CVICU with a diagnosis of congenital or acquired heart disease and an expected length of hospital stay of at least one week. An order from the patient's attending physician/practitioner was required. In order for the child to participate in the study, the child needed to demonstrate stable hemodynamics when ambulating. Children who were extremely immunosuppressed (e.g. status/post Rituxan treatment) were not eligible to participate in the study due to their greater, and potentially fatal, risk for infection. Children with known allergies to dogs, who were fearful of dogs, who were on isolation precautions due to infectious reasons, or who were diagnosed with a global developmental delay were also excluded.

Dog/handler team guidelines

The incorporation of an AAI program into the pediatric hospital setting requires close attention to minimizing the potential but unlikely risks of zoonosis, allergies, animal bites, or physical injury such as tripping or falling while walking an animal (Murthy et al., 2015). All dogs participating in this pilot study were certified through Pet Partners®, a national AAI organization, and were active members of Pet Partners of Central Arkansas and the Arkansas Children's Hospital T.A.I.L.S. (Therapeutic Animal Intervention Lifts Spirits) program (Fig. 1). Table 1 lists standard guidelines for dog/handler teams who participate in AAI activities in the hospital setting.

Procedures

After approval to conduct this pilot study was obtained from the Nursing Research Council at Arkansas Children's Hospital and the Institutional Review Board of The University of Arkansas for Medical Sciences, the study team made regular rounds on the unit to identify eligible subjects. After eligibility criteria was confirmed, written parental informed consent, Health Insurance Portability and Accountability Act (HIPAA), and child assent was obtained.

AAI study sessions started with an aspect of walking. The walking session continued until the subject indicated they wanted to stop or until the Child Life Specialist (CLS) determined that the subject was fatigued or had exceeded medical endurance limits. Additional goal directed therapy activities that incorporated the dog (e.g. petting, grooming) were conducted for the remainder of the 30-min AAI session.

Non-AAI study sessions also started with an aspect of walking and mirrored the AAI sessions with the exception that no dog/handler team was present. For any time remaining after the subject walked, the CLS incorporated play activities at the bedside such as games and arts and crafts.

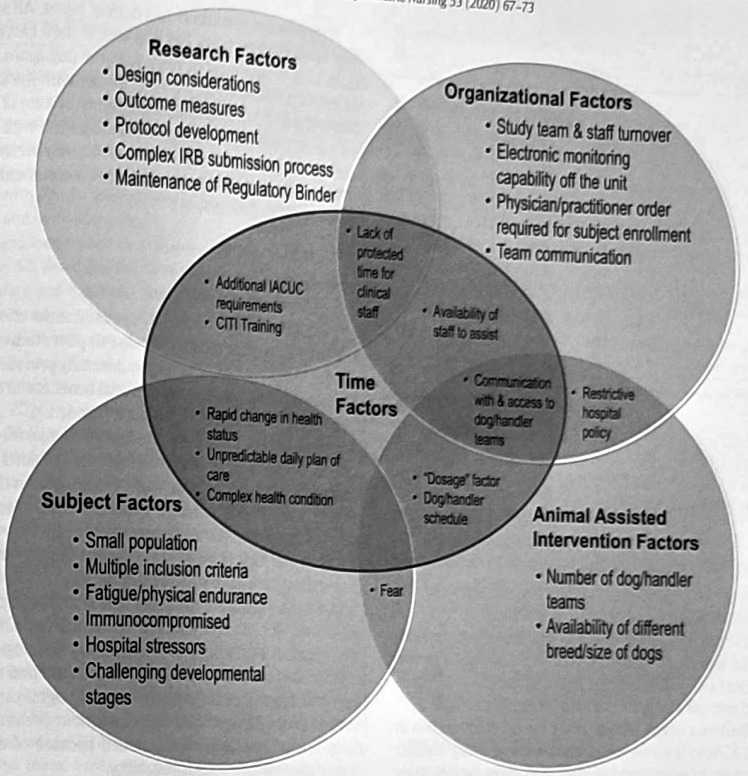

Fig. 1. Model of challenges of implementing AAI research in the hospital setting.

Instruments

Ambulation data

Total time in minutes (min) and distance in feet (ft) were measured with a stopwatch and calibrated rolling measuring wheel starting at the threshold of the subject's room.

Physiologic data

The subject's blood pressure and respiratory rate was obtained prior to the dog entering the room and prior to the dog exiting the room for all AAI sessions and at the beginning and end of all non-AAI study sessions.

Table 1
Guidelines for dog/handler teams.

- All handlers should complete volunteer onboarding and annual health requirements according to hospital policy.
- Handlers should be educated in recognizing signs of fatigue and/or stress in their animals; if present, stressed dogs must be removed from the visit.
- All dogs should be certified through an AAI organization such as Pet Partners® and comply with hospital guidelines for AAI.
- All dogs must be healthy, current on vaccinations, and under the regular care of a veterinarian.
- Dogs should be bathed and groomed prior to the visit in order to minimize allergic responses of subjects by removing as much loose hair, dander, and other debris as possible.
- Patients/study subjects and all healthcare personnel should practice hand hygiene before and after each interaction with the dog/handler team.
- Dog breed and size should be chosen based on patient/study subject preference, if possible.
- For safety, all dogs should have a single lead with two handles while walking with patients/study subjects. The dog handler should hold the handle closest to the dog while the patient/study subject holds the handle farthest from the dog.

Abbreviations: animal-assisted intervention (AAI).

Subject Satisfaction Questionnaire

Patient satisfaction was assessed with the Subject Satisfaction Questionnaire, a four-item self-developed survey to evaluate the satisfaction of subjects during AAI study sessions. Subjects responded to three statements: 1) I liked working with the dog; 2) I walked further with the dog than without the dog; and, 3) If I come to the hospital again, I want to work with the dog. Response choices to these statements were: "No"; "I don't know/I don't care"; or "Yes". The subject also responded to an open-ended question: "Is there anything else you want us to know about working with the dog today?" The questionnaire was administered at the end of the AAI study session.

Child Life Specialist Questionnaire

The Child Life Specialist Questionnaire consisted of a 5-item survey that was administered at the end of the AAI study session in which the dog/handler team was present. Wu et al. (2002) developed the instrument to evaluate the impact of AAI on children hospitalized on a pediatric cardiology unit but did not perform an assessment of the instrument's validity or reliability. The survey questions ask the CLS to rate the subject's activity, rapport, feelings, hospital milieu, and the perceived benefit of the AAI session to the subject.

Statistical methods

This pilot study used a two-period, two-sequence cross-over design. The primary endpoints were ambulation time and distance. Secondary endpoints included the subject's blood pressure, respiratory rate,

Table 2
Demographic characteristics, n = 5.

Age	
Mean (SD)	14.80 (1.64)
Gender; N (%)	
Male	3 (60.0%)
Female	2 (40.0%)
Race; N (%)	
Caucasian/White	3 (60.0%)
African American/Black	1 (20.0%)
Hispanic/Latino	1 (20.0%)
Diagnosis	
Subject 2: S/P heart transplant × 2, hospitalized with graft failure and renal failure	
Subject 3: S/P heart transplant	
Subject 4: Hypoplastic left heart syndrome, S/P Fontan, recurrent PLE	
Subject 5: S/P heart transplant, rejection	
Subject 6: S/P heart transplant, rejection	

Abbreviations: protein-losing enteropathy (PLE); status post (S/P).

subject satisfaction, and perceived benefits of AAI for subjects. Due to low study accrual, only descriptive statistics including frequency counts, proportions, and measures of central tendency and dispersion will be used to describe the results.

Results

Between January 2017 and June 2019, only five subjects were successfully recruited to participate in this study. In August 2017, due to low study accrual, the protocol was modified to shorten the number of study sessions from four study sessions over two weeks to two study sessions over one week. Average age of subjects was 15 years. Three males and two females participated in the study (see Table 2).

Subjects walked on average 1906 ft during the AAI study session as compared to 1933 ft in the non-AAI session without a dog/handler team. Subjects spent a longer time (17 min) walking in the AAI study session with a dog/handler team as compared to the non-AAI study session (15 min). Only one patient required moderate assistance with ambulation (see Table 3).

Mean systolic pressures during AAI sessions (120–122 mm Hg) tended to be lower than mean systolic pressures at the start of non-AAI study sessions (136 mm Hg) and mean systolic pressures at the end of the non-AAI study sessions (126 mm Hg). Mean diastolic blood pressures at the start of the AAI sessions were higher (76 mm Hg) than mean diastolic blood pressures at the end of the AAI session (68 mm Hg) and were similar to diastolic pressures during non-AAI sessions (76–77 mm Hg). Mean respiratory rates ranged between 21 and 25 breaths per minute during all study sessions.

Table 3
Ambulation & therapeutic activities results.

Distance walked (AAI), feet (n = 5)	
Mean (SD)	1906.0 (1812.8)
Distance walked (non-AAI), feet (n = 5)	
Mean (SD)	1932.7 (1855.2)
Time walked (AAI), minutes (n = 5)	
Mean (SD)	17.2 (10.3)
Time walked (non-AAI), minutes (n = 5)	
Mean (SD)	14.7 (9.6)
Assistance score with ambulation (AAI), (n = 5); N (%)	
Minimal assistance	4 (80.0%)
Moderate assistance	1 (20.0%)
Assistance score with ambulation (non-AAI), (n = 5); N (%)	
Minimal assistance	4 (80.0%)
Moderate assistance	1 (20.0%)
Therapeutic activities (AAI), (n = 4); N (%)	
Petting	4 (100.0%)
Grooming	1 (25.0%)
Therapeutic activities (non-AAI), (n = 4); N (%)	
Arts and crafts	2 (50.0%)
Games	2 (50.0%)

Abbreviations: animal-assisted intervention (AAI); standard deviation (SD).

Sixty percent of subjects had dogs at home. All subjects reported they liked working with the dog and, if they came to the hospital again, they would want to work with the dog again. Sixty percent of the subjects perceived they walked further with the dog/handler team than without the dog/handler team. Eighty percent of subjects actively engaged in physical contact and communication with the dog. The CLS reported that the AAI study session was a new welcomed distraction (40%) and that it helped normalize the environment making it more homelike (60%) (see Table 4).

Discussion

This was the first known study to examine the effect of AAI in pediatric heart transplant patients. While this pilot study was fraught with multiple methodological challenges, this study provides preliminary evidence that AAI has positive psychosocial benefits and can be conducted safely in the pediatric heart transplant population.

As physical endurance is a key functional goal for heart transplant patients, having a dog to walk with motivated subjects to engage in ambulation. While mean distance walked was higher in the non-AAI study sessions, subjects walked longer with the dog/handler team. The study team postulates that the excitement and interaction with the dog/handler team may have slowed the pace of the subject but resulted in subjects walking for a longer period of time.

In a meta-analysis of the effect of AAI on physiological responses, Ein, Li, and Vickers (2018) did not find significant differences in blood pressure after AAI. Although differences in physiologic measures were noted in this study, changes in blood pressure and respiratory rates were not deemed to be hemodynamically significant. Subjects who were ambulating were able to talk without breathlessness and no study session had to be discontinued because of dyspnea, oxygen desaturations or physiologic instability.

Incorporating animals into the complex CVICU environment helped to normalize the hospital environment and provide distraction from their stressful disease trajectories. Subjects in this study were eager to walk with the dog/handler team. The AAI opportunity provided both psychosocial support and helped the subject to meet their daily physical therapy goal for ambulation.

Although the effects derived after a single AAI intervention is unknown, the subjects who participated in this study derived intense satisfaction from the AAI experience. Box 1 provides a case report of an

Table 4
Child life specialist questionnaire results.

Category	N (%)
Activity	
Physical contact initiated or accepted	4 (80.0%)
Active play	1 (20.0%)
Rapport	
Interaction is warm, friendly, and open	1 (20.0%)
Interaction is loving and intimate	4 (80.0%)
Feelings	
Pleased and content	3 (60.0%)
Happy and joyful	2 (40.0%)
Milieu/social environment	
Distraction: described as "something new," "a diversion," etc.	2 (40.0%)
Normalization: described as "more homelike," "something familiar," etc.	3 (60.0%)
Benefit	
Motivation/facilitation: gives motivation to get better, comply with treatment; facilitates social interaction, provides topics of conversation, etc.	1 (20.0%)
Unconditional love: gives feelings of love, acceptance, need, and value	1 (20.0%)
Object of comfort/projection of feelings: gives sense of control, offers opportunity to release fears and worries	3 (60.0%)

Modified From: Wu et al., 2002. Acceptability and impact of pet visitation on a pediatric cardiology inpatient unit. Journal of Pediatric Nursing, 17(5), 357. Used with permission.

Box 1
Case Report of AAI in an Adolescent Pediatric Heart Transplant Patient

A 16-year-old African American female was hospitalized in the pediatric CVICU for graft failure and renal failure following her second heart transplant. The subject had a long history of complications resulting from her CHD including dilated cardiomyopathy, end-stage renal disease requiring nightly peritoneal dialysis, diabetes with insulin insensitivity, cyclic vomiting, adrenal insufficiency, and hyperlipidemia.

The subject described herself as a "country girl from Mississippi". When she was 10 years old, her family learned that she needed a heart transplant and the entire family including her mother, father, and four teenage siblings left their home in Mississippi to move closer to the heart transplant center at Arkansas Children's Hospital in Little Rock, Arkansas. Following graft failure after her first heart transplant, the subject received her second heart transplant in April, 2011. Over the next eight years, the subject encountered frequent extended hospitalizations in the CVICU for graft and renal failure. Common to many hospitalized teens who often feel a loss of control over their lives, privacy, and environment, the subject was anxious and often resisted healthcare providers' efforts to ambulate and engage in therapeutic activities. However, when presented with the opportunity to participate in the AAI research, the patient eagerly agreed to study participation. As the mother was fearful of dogs, a small dog was chosen for this subject. The therapy dog was a 5-year-old male longhair Dachshund weighing approximately 15 pounds (see Fig. 2).

The CLS reported that the subject was eager to get out of bed to walk with the dog during the AAI session. The subject walked a distance of 1422 feet during the study session with the dog/handler team compared to 1307 feet during the study session without the dog/handler team. While this subject only walked approximately 115 feet farther with the dog, ambulation distance during the study sessions was in sharp contrast to this subject's baseline where she typically walked only about 350 to 500 feet during her regular physical therapy sessions.

The duration of time walked also varied between the study sessions. The subject walked 24 minutes during the AAI session compared to 15 minutes during the non-AAI session.

Blood pressure was taken before and after each therapy session. The subject's blood pressure decreased from 131/87 to 117/69 during the AAI study session. In the non-AAI session without the dog/handler team, the subject's blood pressure was 119/95 prior to ambulation and 120/79 at completion of the study session.

The subject described her milieu as "something new" and a welcomed "diversion" in the hospital routine. The CLS noted that the dog/handler session gave the subject motivation to get better and comply with her prescribed medical treatment. Improvement was noted in the subject's concentration/attention, socialization/engagement, mood/anxiety level, and communication. The subject stated, if given the opportunity, she would like to work with the dog again in the future.

Abbreviations: animal-assisted intervention (AAI); Cardiovascular Intensive Care Unit (CVICU); Child Life Specialist (CLS); congenital heart disease (CHD)

adolescent female subject hospitalized for graft failure and renal failure following her second heart transplant. She was eager to get out of bed and walked significantly longer and further than her baseline ambulation.

No falls, infections, injuries, or other safety-related adverse events occurred during this AAI study. Several clinical studies have examined infection outcomes associated with AAI and have not found any increase risk of infection (Caprilli & Messeri, 2006; Khan & Farrag, 2000; Lerner-Durjava, 1994; Snipelisky & Burton, 2014).

Challenges/lessons learned

Clinical research studies are often fraught with many real-world clinical challenges. Although research designs attempt to control for extraneous variables that might impact the results of the study, clinical research has often been termed "messy" from the researcher's inability to systematically control for every healthcare system factor that may hinder research procedures and influence study outcomes.

In an attempt to better understand the methodological challenges of conducting AAI research in critical care, a conceptual model is introduced. The key components that should be considered are research factors, organizational factors, AAI factors, subject factors and time factors. The research component comprises study design and research related processes. The organizational component relates to healthcare system issues and factors that influence the conduct of research including policies, hospital culture, personnel and resources. The AAI component discusses issues related to dog/handler teams. The subject component focuses on patient population characteristics that should be considered when enrolling subjects. The final component illustrates how time is central to all AAI methodological challenges and overlaps with the other four key components. The time component takes into account factors such as protected time for staff to participate in research, the time-laden research training requirements, and scheduling complexities. While it is well recognized that many more factors exist that potentially create challenges when conducting AAI research, the five components presented in this model are hypothesized to have the most direct impact on this type of research (see Fig. 2).

Research factors

It is widely acknowledged that the gold standard for research design is the randomized controlled trial where subjects are assigned to either an intervention group or a control group, by chance. However, implementing a randomized controlled trial of AAI in a pediatric hospital setting where a group of children would not have access to AAI would be considered unethical by most clinicians and researchers. Another design issue of implementing a randomized controlled trial in AAI research is the inability to blind subjects to treatment group (e.g. the AAI group vs. non-AAI control group). Therefore, the study team selected to use a two-period, two-sequence cross-over design that allowed each subject to serve as his/her own control.

A methodological limitation in this pilot study and in the AAI research literature in general is a lack of outcome measures using reliable and validated scales. Many studies tend to use outcomes that rely on self-reporting by participants or subjective observations of staff that may bias study findings. Rigorous scientific research is needed using more objective measures and attention to developing instruments that have established psychometric properties.

Another research challenge is the lack of training clinical staff receives in developing, implementing, and monitoring study-related activities. While most academic programs cover basic research principles, many programs do not provide the student with real world application experiences necessary to develop all aspects of the research protocol, navigate the research approval process, and implement and monitor the integrity of the study. It is important that healthcare organizations have Nursing Research Departments that offer research education and mentors to assist and support clinical staff desiring to participate and/or conduct clinical research.

Organizational factors

Engaging clinical nurses in research is essential to strengthening the scientific foundation of nursing and ensuring that nursing research is

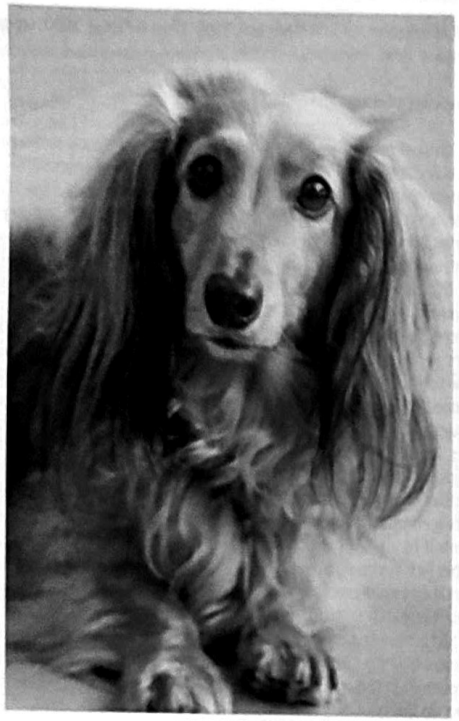

Fig. 2. Winston, therapy dog.

applicable to nursing practice but continues to be a challenge. Nurses lack of confidence in their research knowledge and skills can often interfere with their participation in research (Hagan & Walden, 2015). Many nurses may also falsely assume that participation in research only consists of designing and implementing study protocols. However, there are many ways that nurses participate in research including: conducting studies, serving on study teams; identifying clinical practice issues needing evidence; participating in recruiting subjects for studies; completing data collection for ongoing studies; coordinating care to ensure subjects are ready for their study sessions; disseminating research findings; and, translating research findings into practice. Nurses are responsible for helping to ensure the safe and ethical conduct of research related to their patient by making sure both the parent and patient have provided written consent/assent and that a copy of the informed consent/assent is in the patient's medical record. The clinical nurse should also be familiar with the study purpose and general protocol procedures. The subject's nurse played an important role in this study by helping prepare the subject for their study session and organizing the patient's daily plan of care to ensure that other caregiving priorities were completed. Clinical nurses embraced the AAI study sessions as the opportunity to walk with a dog was not only a motivation to get the patient to ambulate, but the dog also provided a therapeutic distraction from pain, anxiety and other stressors related to the subject's diagnosis, prognosis and hospitalization.

An organizational challenge encountered in the study was lack of awareness of the electronic monitoring capability of vital signs in certain areas of the hospital. The study protocol included plans to measure heart rate and oxygen saturation. However, the study team found that this electronic data were not captured during ambulation outside of the CVICU. It is important that the study team regularly investigate the institution's physiologic data capture capability prior to and throughout the data collection period. Future research should consider alternative methods to capture this data such as wearable devices and wireless monitors.

Team communication is often one of the most challenging organizational factors. An example of communication and scheduling challenges occurred when the dialysis team changed their scheduled time, failed to communicate with the research team, and thus required the AAI session to be postponed and rescheduled.

AAI factors

One of the most common challenges in AAI research is the fear of transmission of zoonotic diseases, allergies and injuries. This was a particular concern in this highly immunocompromised heart transplant population. Since the T.A.I.L.S. program inception at Arkansas Children's Hospital in 2001, there have been no reported patient injuries or no increase number of hospital-acquired infections that can be attributable to the AAI program. The increase in patient experience provided by the program greatly outweighs the potential but rare risk of adverse events of AAI in the hospital setting.

Another challenge sometimes encountered in AAI research is the patient or family's fear of dogs. In this study, one subject loved animals but her mother had an intense fear of dogs. The subject's mother eventually agreed to allow her daughter to participate in the study; however, she preferred to not be present when the dog/handler team was in the room. A small dog was selected by the study team in an attempt to minimize the mother's fear of dogs.

Conducting AAI research requires access to a large cohort of dog/handler teams of various size and breeds of dogs that are available to visit at different times and days throughout the week. The CVICU environment posed a difficult challenge in terms of scheduling patients who had complex medical intervention needs coupled with ensuring the concurrent availability of a CLS, the research team, and a dog/handler team.

Subject factors

Similar to the study by Novotny et al. (2015), recruitment of patients who met study eligibility criteria was a challenge. During study accrual, the organization experienced a decrease in heart transplant patients while additional cardiovascular surgeons were hired and onboarded. After eight months of failed study enrollment, the age range and study duration times were modified in an attempt to increase recruitment of subjects from the available pool of patients admitted to the CVICU. Unfortunately, 30 months later, the study was formally closed due to low study accrual numbers. The decision to halt the study due to low enrollment was very difficult for team members considering the amount of effort that had been expended to develop and implement the protocol and recruit subjects. Closure of study protocols is particularly difficult for clinical nurses who become easily discouraged with the research process.

One obstacle that coincides with the nature of the CVICU environment was times that the patient's medical status prevented their participation. For example, one subject was having her percutaneous central line dressing changed when the study session was scheduled, thus requiring the AAI session to be postponed and rescheduled to a later date. In another example, the team met with scheduling conflicts when a physical therapist had the patient exercise prior to the study session. The scheduled study session had to be postponed in order to mitigate the potential of skewed data, as the patient was already fatigued.

Time factors

One of the first challenges the study team encountered was the unanticipated need to seek research approval from the Institutional Animal Care and Use Committee (IACUC) as well as from the Institutional Review Board overseeing the conduct of human research studies. In addition to extensive Collaborative Institutional Training Initiative (CITI) requirements for both human and animal research, the study team was also required to attend an animal research certification class and complete a health screening with Occupational Health. This was a substantial time commitment for researchers but an added burden for clinical staff that often have limited protected time to complete such activities.

Another limiting factor that presented a challenge in this study population was the "dosage" factor. The scheduling difficulties encountered to ensure the concurrent availability of research personnel, the CLS, and the dog/handler team coupled with the complexity of the subject's medical therapies and complex critical care environment only allowed for one study session with the dog/handler team and one study session without the dog/handler team over a period of one week. Future research should consider longitudinal designs that maximize the "dosage" factor and allows for increased frequency of study sessions over a longer period of time.

Conclusion

Research suggests positive impacts of AAI for adults and children with a variety of medical and psychological conditions. While many challenges exist in implementing AAI research in the pediatric heart transplant population in the CVICU, the potential benefits outweigh the theorized risks. This pilot study provides evidence that AAI may assist adolescent heart transplant patients to be more motivated to participate in therapeutic ambulation when walking with a dog. Further studies are needed to identify successful recruitment strategies in this highly vulnerable patient population. Rigorous research is needed to establish the effectiveness of AAI in adolescents' pre- and post-heart transplantation.

Author statement

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Marlene Walden: Conceptualization, Methodology, Formal analysis, Investigation, Writing - original draft, Writing - review & editing, Supervision, **Austin Lovenstein:** Conceptualization, Methodology, Formal analysis, Investigation, Project administration, Writing - original draft, Writing - review & editing, **Amelia Randag:** Conceptualization, Investigation, Writing - original draft, Writing - review & editing, **Sherry Pye:** Conceptualization, Writing - original draft, Writing - review & editing, **Brianna Shannon:** Investigation, Writing - original draft, Writing - review & editing, **Esther Pipkin:** Conceptualization, Resources, Writing - review & editing, **Amy Ramick:** Investigation, Writing - original draft, Writing - review & editing, **Keri Helmick:** Investigation, Writing - review & editing, **Margaret Strickland:** Investigation, Writing - review & editing.

Declaration of competing interest

None.

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