Animal assisted interactions with an animal robot during physical and occupational therapy sessions in the Pediatric ICU: A feasibility study (PCRG)

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Study Protocol

Purpose

The purpose of this study is to evaluate the feasibility, acceptability, safety, and preliminary therapeutic treatment effects of PARO™, a therapeutic animal robot, during physical therapy and occupational therapy sessions with critically ill patients in the Pediatric ICU (PICU).

Background & Rationale

Symptom Experience in the PICU: Admission to the PICU can be an extremely upsetting experience for children of all ages. In addition to physical symptoms such as pain, thirst and fatigue, patients in the PICU also experience a multitude of psychological symptoms. Symptoms like anxiety, spells of terror, social isolation, disturbed sleeping patterns, restlessness, fear, confusion and loss of control are exacerbated in the PICU because patients often have limited mobility, decreased capacity to communicate, and rely on healthcare providers for survival.

Symptom Management in the PICU: Large doses of sedative and analgesic medications are administered by nursing staff to help alleviate distressing symptoms. Overuse of sedative medications can cause a sequelae of adverse effects and, therefore, recent recommendations call for reducing sedative use as much as possible. To minimize the overwhelming symptom burden of acute critical illness and promote lasting psychological well-being during recovery, it is imperative to identify effective non-pharmacological interventions that decrease psychological distress, but do not alter level of alertness during acute critical illness. Established evidence supports the use of a variety of non-pharmacological approaches that can be easily applied as adjuncts to sedative and analgesic medications in order to reduce dependence on these medications. Animal assisted interactions (AAI) are a promising integrative approach that can be used as an adjunct to sedative and analgesic medications in order to improve psychological symptoms and promote comfort, relaxation, and positive mood in critically ill patients.

AAI to Alleviate Symptoms in the ICU: AAI are interventions that intentionally incorporate animals as part of a therapeutic process to promote human health, learning, and well-being. Domestic and farm animals such as dogs, cats, birds, equines, guinea pigs, rabbits, llamas, sheep, goats, and pigs are predominantly featured in AAI programs. Animals can be simply observed, touched, held, and petted, or more actively integrated into specific therapy activities such as brushing with different tools to exercise range of motion and fine motor coordination and tandem walking with the animal to encourage exercise. Recent literature indicates that AAI can improve reality orientation and attention span, eliminate the sense of isolation, reduce stress and anxiety, enhance communication, promote positive social interactions, and enhance overall quality of life. The use of AAI in the ICU has the potential to engage patients, family members, and healthcare staff in an innovative, holistic approach to symptom management.

Benefits of Robotic Animals for AAI in the ICU: While additional research is warranted to further explore the potential impact of AAI on a variety of clinically meaningful patient outcomes, the highly technical, fast-paced ICU environment and the severely immunocompromised health statuses of ICU patients greatly limits the exploration of AAI in the ICU. A new frontier in animal robotics opens a vast array of opportunities to implement AAI in the critically ill population. Robot animals may be just as effective as live animals and may provide even more flexibility and tailoring in order to meet the needs of diverse

situation that arise in the ICU. In addition, the infection control risk that live animals pose to critically ill patients may be significantly lessened.

Methods

At the patient's first physical/occupational (PT/OT) appointment, the PT/OT provider will assess whether eligibility criteria are met. If so, the study will be presented to the patient and their parent or guardian. If the patient is interested in participating, the PI or PI's research assistant (RA) will obtain written informed consent. Pretest data collection is next, followed by the therapy session with PARO. The PI or RA will remain in the room during therapy session to record field notes. After completion of the therapy session, the PI or RA will begin post-test data collection. The participant will remain in the study for up to 7 PT/OT sessions or until discharge from the PICU.

The Patient Demographic Form will be administered to all participants prior to the initial PT/OT session with PARO. Data specific to the PARO intervention (Psychological and Physiological Variables, Activity Performance), will be collected via a face-to-face interview within 30 minutes prior to and within 30 minutes after each PT/OT session with PARO. ATP testing will occur prior to each new subject enrollment to ensure participant safety. Semi-structured interviews will be conducted with the participant and an intervention satisfaction measure will be administered after the protocol is complete (either after 7 PT/OT sessions with PARO or at ICU discharge).

Only one participant will be enrolled at a time. Participants & therapists will be required to practice hand hygiene before and after use of PARO. During the protocol, PARO will be kept in a hard plastic pet carrier which is brought to the participant's room for the PT/OT sessions. A sheet or towel will be placed under PARO anytime it is placed on a bed, table, chair, etc. to avoid direct contact with surfaces in the room. Once the PT/OT session is done, the PARO is returned to the PI's office in the carrier. The PARO is removed from the carrier, which is cleaned with a PDI Super Sani-Cloth wipe. The PARO is then cleaned per the Daily Cleaning Protocol**.** This entails moving a Rapid Razor-UV™ cordless handheld sanitizer over the entire PARO surface, pausing over each area for 20 to 30 seconds. The PARO is returned to the carrier after cleaning.

Prior to a new enrollment or if the PARO is visibly soiled, it will be deep cleaned per the Deep Cleaning Protocol**.** This involves spraying the PARO's fur with Dapple cleaner and wiping with a towel, avoiding the area around eyes and nose. Next the fur is wiped with a PDI Super Sani-Cloth and left to dry. Lastly, the fur is brushed with a brush sprayed with Clorox bleach and allowed to dry again. Cleanliness is tested by swabbing 14 locations on the PARO which are checked with the ATP monitoring system with SystemSURE Plus Process. All test results must be below the established RLU threshold of 30. If any of the areas tested do not meet the threshold, the entire PARO will be cleaned again. Once all areas tested fall below the 30 RLU threshold, the PARO is placed in its carrier.

Statistical Analysis Plan

Sample Size

Prior studies of PARO™ in other non-ICU settings have shown moderate to large effect sizes. A sample in the range of 20-25 is adequate for single-group efficacy studies when population effect sizes are likely to be moderate or larger. Since we are unsure of the exact expected effect size in the ICU, we have increased our sample size to 30.

Analysis

All data collected will be entered directly into REDCap and exported into SPSS 24 for data analysis. For Aim 1, establishing the feasibility and acceptability of PARO™ for critically ill patients admitted to the PICU, feasibility will be calculated by comparing total consent and refusal rates, attrition rates, and the number of full therapy sessions completed. Refusal and attrition rates will be evaluated using point estimates and confidence intervals. Intervention acceptability will be assessed by summarizing scores from the Patient Satisfaction Measure. Descriptive statistics will be used to summarize individual scores, including mean, standard deviation, range, median, and interquartile range. A content analysis on the results from the semi-structured interviews will be conducted.

For Aim 2, exploring safety considerations related to infection control [participant hospital-acquired infection (HAI) rates, screening for the presence of microbial contamination with real-time ATP testing], any hospital acquired infection obtained while in the PICU will be tracked. The ATP scores after each deep cleaning session will be plotted for graphical trends.

For Aim 3, examining the therapeutic effect of PARO on patient psychological variables (pain, anxiety) physiological variables (heart rate, blood pressure, respiratory rate, oxygen saturation), and sedative and analgesic medication requirements will be recorded pre- and post-test. These scores will be summarized using descriptive statistics and the distributions of psychological and physical variables will be assessed for normality. Therapeutic effects for normally distributed variables will be assessed with paired samples t-tests to assess changes as a result of PARO. Wilcoxon signed rank tests will be used for variables found to be non-normal.