Therapeutic Play Intervention

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RANDOMIZED CONTROLLED TRIAL (RCT) is the gold standard in research. However, few nurse scientists conduct RCTs, when compared with other types of research designs. One legitimate explanation is the lack of true control when working in a clinical setting. Manipulating mice and controlling human patients are obviously two very different challenges. Nevertheless, as our health care system demands cost-effective, clinically significant, and feasible interventions, nurses have the opportunity to make important contributions as lead investigators in RCTs. The following two articles present different perspectives of a single trial, led by a team of nurse researchers from Singapore, Australia, and China.

Therapeutic play intervention on children's perioperative anxiety, negative emotional manifestation, and postoperative pain: A randomized controlled trial by He H-G, Zhu L, Chan W-CS, et al. *Journal of Advanced Nursing*. 2015; 71:1032-1043.

Background and Purpose

Children and their parents endure at least some angst when the child is scheduled for surgery. This first of two reports focuses on the children's experience. Specifically, a child's anxiety surrounding surgery can lead to negative emotional manifestations, including lack of cooperation with health care providers in the perianesthesia settings. In addition to anxiety and subsequent expressions, children often have pain postoperatively. The authors reported inadequate management of pain in some children undergoing surgery in Singapore.

Therapeutic play has been shown to reduce children's anxiety, increase their sense of control, and educate regarding anticipated procedures or hospitalizations. This approach is not new. Unfortunately, the authors found only six RCTs that examined effectiveness of therapeutic play in children having surgery. Among those six, the findings and conclusions were inconsistent; thereby, leaving a gap in the knowledge of the effects of therapeutic play in this vulnerable population. The overall aim of this study was to examine the efficacy of a therapeutic play intervention on children undergoing elective, inpatient surgery, and their parents. The purpose of this first report was to look closely at the outcomes related to the children: perioperative anxiety, negative emotional manifestation, and postoperative pain. The researchers hypothesized that children who received the intervention would report less anxiety, fewer negative emotional signs, and less pain when compared with a control group that did not receive the intervention.

Methodology

As noted earlier, researchers designed a longitudinal, two-group RCT. One group received the therapeutic play intervention, and the other (control) group received the standard of care plus some educational materials. As potential participants were identified and recruited, they were randomly assigned to one of the two groups. Measures were taken at three points: 3 to 7 days before surgery; preoperatively on the day of surgery; and 24 hours postoperatively.

Recruitment took place for more than a period of 21 months from 2011 to 2013. Inclusion criteria for the children were 6 to 14 years old, scheduled for inpatient elective surgery, fluent in English or Mandarin, with at least one parent present in the hospital. Children with a history of previous

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surgeries, long-term illness or pain, or disabilities were excluded from the study.

Consistent with good intervention research, the authors had previously conducted a pilot study to determine the appropriate sample size needed for the RCT. They also accounted for a 20% attrition rate. On the basis of that analysis and their desire to detect a medium effect of the intervention, they aimed to recruit 106 children or 53 in each group.

Children who were randomly assigned to the intervention (treatment) group participated in a 1-hour session with a researcher who guided the therapeutic play. The child received a manual that included images and information about medical equipment related to their upcoming operation. This took place at the outpatient clinic or at the child's home, depending on parent preference. The child watched a video on preparing for the operation. They looked at photographs of the hospital and surgery environment and did return demonstrations on some procedures, eg, receiving anesthesia therapy, using dolls. Parents could participate in the intervention, but most of them sat quietly when the researcher and child interacted. The families received an oxygen mask and intravenous cannula (without the needle) to take home.

Outcome measures were collected using the following:

1. Demographic information was self-reported by children and parents. Clinical information, eg, type of surgery, duration of surgery, use of analgesia 24 hours postoperatively, was documented from the child's medical record.
2. Perioperative anxiety: State Anxiety Scale for Children (SAS-C), a short form of the State-Trait-Anxiety Inventory for Children, captured state anxiety. Five of the 10 items on the SAS-C assess negative emotions; the other five assess positive emotions. Using a scale of 1 to 3, scores ranged from 10 to 30, with higher scores representing higher levels of anxiety. Children were able to choose the English or Mandarin version of the SAS-C to answer the 10 questions.
3. Negative emotional manifestations: Children's Emotional Manifestation Scale (CEMS) measured this outcome. The CEMS captures five emotional behaviors: facial expression, vocalization, activity, interaction, and level of cooperation. Using a scale of 1 to 5, the total scores ranged from 5 to 25, with high scores indicating greater severity of negative emotional manifestations. Nurse researchers recorded these findings.
4. Postoperative pain: The Numeric Rating Scale measured pain intensity from 0 (no pain) to 10 (worst pain).

The participating hospital provided the list of scheduled surgeries to the researchers. Parents of potential patient participants were contacted via phone and mail. If eligible and agreeable, children were randomly assigned to one of the two groups, and they were told of their allocation via phone. At time one, 3 to 7 days before surgery, the treatment group completed demographics and participated in the intervention. Those in the control group completed their baseline data through the mail.

On the day of surgery, measure time two, all child participants completed the SAS-C. In addition, research assistants, blinded to group allocation, completed the CEMS on all child participants. Likewise, postoperative pain data were collected approximately 24 hours after surgery or before discharge, whichever came first.

Data were analyzed using popular statistical software. Descriptive statistics and scores on the three study outcomes were reported. In addition, the authors included a diagram depicting the recruitment and measurement points. Although 53 children were initially in the experimental group and received the therapeutic play intervention, five were excluded because of postponement of surgery (n = 1), diagnosis of autism (n = 1), previous surgeries (n = 1), or family choice (n = 2). In the control group, six of the 53 children were excluded because of delayed surgery (n = 3), canceled surgery (n = 1), previous surgery (n = 1), or family choice (n = 1). Therefore, a total of 95 participants were included in the analysis.