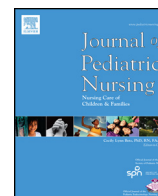




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Randomized Trial Evaluating the Effectiveness of Coloring on Decreasing Anxiety Among Parents in a Pediatric Surgical Waiting Area

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ABSTRACT

Anxiety is common among pediatric surgical patients and their parents. Numerous studies have examined interventions to reduce pediatric patients' anxiety; however, less is known about reducing parental anxiety. In other populations, producing art has been shown to significantly reduce anxiety.

Purpose: This study aimed to determine whether parents' anxiety decreased after coloring while their child is in surgery.

Design and Methods: A block randomized controlled trial was conducted with a convenience sample of 106 parents of children who were having a scheduled surgery. Each day of data collection was randomized where all parents enrolled that day would either color a pre-drawn art template for 30 min or would simply wait in the waiting room for 30 min. The primary outcome measure was anxiety, measured by the 6-item short form of the Spielberger State Trait Anxiety Inventory (STAI).

Results: Parents' average anxiety score decreased from the initial measurement to the measurement 30 min later in both the control group and the intervention group. The reduction in anxiety was significantly greater for those parents who participated in coloring during their wait ($p < 0.0001$).

Conclusions: Coloring is a creative, simple, low cost, and effective activity to reduce anxiety among parents in a pediatric surgical waiting area.

Practice Implications: Providing coloring materials and information about the benefits of coloring in pediatric surgery waiting areas is an easy to implement intervention to reduce parental anxiety.

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Anxiety is common among pediatric surgical patients and their parents. High preoperative anxiety among pediatric surgery patients is related to lower levels of cooperation during induction (Li & Lam, 2003), lower levels of cooperation postoperatively (Li & Lam, 2003) and increased pain postoperatively (Esteve, Marquina-Aponte, & Ramirez-Maestre, 2014; Fortier, Del Rosario, Martin, & Kain, 2010). There have been numerous studies examining interventions to reduce pediatric patients' anxiety before surgery including distraction with a tablet (Seiden et al., 2014), cartoon or video distraction (Kerimoglu, Neuman, Paul, Stefanov, & Twersky, 2013; Lee et al., 2012; Mifflin, Hackmann, & Chorney, 2012), and preoperative programs (Cuzzocrea et al., 2013). While these interventions have demonstrated varying success at reducing pediatric patients' anxiety, they do not address their parents who also report high levels of anxiety. Interestingly, there is evidence that

parents' reporting of high anxiety is associated with pediatric patients having high anxiety (Fortier et al., 2010; Kain, Mayes, O'Connor, & Cicchetti, 1996; Li & Lam, 2003). To improve the experience of surgery for both pediatric patients and their parents, one avenue to explore is an intervention to reduce parental anxiety.

Previous research supports the use of creative arts interventions, including coloring, to reduce anxiety. Curry and Kasser (2005) studied coloring as a tool to reduce anxiety in healthy adults. Subjects underwent an anxiety induction protocol and were randomized to either color a mandala, color a plaid form, or color on a blank piece of paper. Anxiety levels decreased with coloring among all groups, with the subjects coloring the mandala and plaid pattern experiencing the largest reduction in anxiety. Van der Venet and Serice (2012) also induced anxiety among healthy adults and then assigned subjects to color a mandala, color a plaid template, or color on a blank piece of paper. They found that all subjects experienced a decrease in anxiety, with the largest reduction experienced by the group that colored on a pre-drawn mandala. Sandmire, Gorham, Rankin, and Grimm (2012) studied healthy adults and compared subjects who created art for

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30 min to control subjects who waited for 30 min. They found that the subjects who produced art experienced a significantly larger decrease in anxiety than the control group. Sandmire et al. (2016) conducted a second study of healthy adults with some subjects participating in 30 min of art making and others waiting for 30 min. They found a significantly greater decrease in anxiety, indicated by an increase in heart rate variability, in the art-making group compared to the control groups. Mouradian, DeGrace, and Thompson (2013) translated these findings from studies of healthy adults to a healthcare setting and found that a creative arts intervention provided to parents of infants admitted to a neonatal intensive care unit resulted in a significant decrease in parent anxiety.

Overall, these findings demonstrate that a brief period of producing art can significantly reduce a person's state of anxiety. However, to date, no study has examined the use of a creative art intervention to reduce anxiety in parents in a pediatric surgery waiting area. The objective of the present study is to examine whether parents who colored while waiting in a surgical waiting room would have decreased anxiety compared to parents who did not color.

Design and Methods

A block randomized, controlled trial was conducted to examine the effect of coloring pre-drawn art templates on parental anxiety level while those parents' children were in surgery. The study took place in a surgical waiting area at a large, urban, mid-western pediatric hospital. Each day there are approximately 60–100 surgeries that are performed, resulting in a full surgical waiting area. Common surgeries performed include ear tube placement, tonsillectomy and adenoidectomy, eye muscle surgeries, orthopedic surgeries, repairs of congenital malformations, and complex dental procedures. Study approval was obtained from the hospital's institutional review board. Study staff completed education on the ethical treatment of human subjects in research before beginning the study.

Sample

A priori power analysis indicated that to detect an effect size of 1.0 with 5% error rate and 99% power, 50 subjects would need to be enrolled in each group for a total sample size of 100. The expected effect size was derived from a previous study (Van der Venet & Serice, 2012). A convenience sample of 106 parents of children who were having a scheduled surgery was enrolled. Parents were excluded if the parent was younger than 18 years old or if their child was undergoing an emergency surgery or having a surgery that was scheduled for <30 min.

Procedures

A block randomization method was used with each day of data collection randomly assigned, using a computer-generated random number list, to be either a “coloring day” or a “no coloring day.” Block randomization was used so all subjects enrolled on the same day would receive the same intervention. This was important to reduce potential bias and contamination that could occur if subjects were randomized individually and would be able to observe some subjects coloring and other subjects not coloring.

All parents who entered the waiting area were approached by study nurses and invited to participate in the study, with the exception of parents who were visibly upset when they entered the waiting area. There were two study nurses, and both were clinical staff of the surgical unit who had been trained in the study protocol, human subjects' protections, and informed consent procedures. Study staff reviewed inclusion and exclusion criteria and explained the study to the patient and family. All parents who met the inclusion criteria were invited to participate and parental pairs were eligible to participate. Interestingly, very few parents from the same family agreed to participate. If parents qualified

for the study and were interested in participating, they were provided a questionnaire asking for demographic information including age, gender, and whether the parent was taking anxiety medication. The questionnaire also assessed baseline anxiety. Anxiety was measured using the 6-item short form of the Spielberger State Trait Anxiety Inventory (STAI). The raw scores of the 6-item STAI were scored to be comparable to the full 20-item STAI. STAI scores range from 20 to 80, with a lower STAI score signifying less anxiety. The 6-item STAI has high reliability and concurrent validity with the full version of the STAI (Marteau & Bekker, 1992). No identifiers were recorded, and the IRB approved a waiver of documentation of informed consent. Therefore, elements of informed consent were included on the questionnaires and consent was implied by participants' completion and submission of the questionnaires.

For subjects enrolled on a “no coloring day,” the study staff waited approximately 30 min after subjects filled out baseline information and then provided them a second 6-item STAI to complete. During the 30 min, subjects were left to sit in the waiting room and engage in any activity they would normally do while waiting. On “coloring days,” after collecting the baseline information, the study staff provided subjects their choice of pre-drawn art templates and colored pencils and invited them to color for approximately 30 min. The setting was identical on both the experimental and control days with chairs and side tables available. Participants were able to sit anywhere they chose and with whoever they chose. At the end of the 30 min, study staff provided the participants' a second 6-item STAI to complete.

Data Analysis Plan

The distributions of all continuous variables were checked prior to analyses to ensure that the assumption of normality was appropriate. Descriptive statistics for the continuous data were calculated as mean \pm SD and the categorical data as percentages. Demographic characteristics for categorical data were compared by chi-square or Fisher exact test and for continuous data by Mann Whitney Rank Sum test to generate the *p*-values for testing the equality between control and intervention groups.

To compare the effects of coloring on level of anxiety, analysis of variance (ANOVA) was used. To compare the difference in anxiety at two time points, before and after surgery, paired sample *t*-test was used. A secondary analysis was used based on multiple regression model to adjust for the subjects' characteristics (age, gender, currently taking anti-anxiety medications, and first experience waiting during surgery). Statistical analyses were performed using SAS (Statistical Analysis Software, version 9.3, SAS Institute Inc., NC, USA) statistical software. In all the statistical testing, the alpha level was set to 0.05.

Results

A total of 106 participants were enrolled in the study, with 52 in the control (no coloring) group and 54 in the intervention (coloring) group. Data were collected on 6 days. The 6 days were randomized to be either “no coloring” or “coloring” days. Participants were 18 years or older, and the majority of participants were female (78%). No statistically significant differences were found in participants' demographics between the control group and the intervention group (see Table 1). The mean anxiety score at baseline was statistically different between the control group and the intervention group, with the intervention group ($M = 49.88, SD = 12.92$) reporting significantly higher anxiety at baseline compared to the control group ($M = 43.79, SD = 13.84$), $t(103) = -2.331, p = 0.022$.

To compare the effects of coloring on anxiety, ANOVA was used (see Table 2). The average anxiety score decreased from the initial measurement to the measurement 30 min later in both the control group (43.79 to 42.09, $p = 0.023$) and the intervention group (49.88 to 39.69, $p < 0.0001$). While parents in both groups experienced reduced anxiety after approximately 30 min, the decrease in anxiety was significantly

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