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Effectiveness of an App for Reducing Preoperative Anxiety in Children
A Randomized Clinical Trial

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IMPORTANCE Effective methods to reduce children's preoperative anxiety (such as giving information beforehand, organizing a tour of the operating room [OR] before the intervention, and incorporating clown physicians) may be difficult to implement for some hospitals, as they are time-consuming and expensive and require hospital staff to be performed.

OBJECTIVE To test the effectiveness of Clickamico, an app that shows clown physicians giving a comical and informative tour of the OR, for reducing preoperative anxiety in children.

DESIGN, SETTING, AND PARTICIPANTS This unblinded randomized clinical trial included 40 children aged 6 to 11 years undergoing a planned surgical intervention at a third-level Italian pediatric hospital from December 2013 to September 2014 randomized into experimental (n = 20) and control (n = 20) groups.

INTERVENTIONS The experimental intervention was a 6-minute video showing 2 clown physicians visiting the OR and explaining to each other what is in the OR in a joking way. The video was shown on a tablet to children in the experimental group the afternoon preceding a planned surgical procedure. The control intervention was the standard informative intervention regarding the surgical procedure the next day.

MAIN OUTCOMES AND MEASURES The main outcome was preoperative anxiety. Preoperative anxiety was measured before the experimental and control interventions and immediately before entering the OR using the modified Yale Preoperative Anxiety Scale (m-YPAS).

RESULTS The experimental and control groups were homogeneous with regard to age (mean [SD] age, 8.8 [2.5] vs 8.6 [2.2] years), sex (female, 11 [55.0%] vs 9 [45.0%]), parents' age (mean [SD] age, 41.8 [6.2] vs 41.3 [5.0] years), and previous surgical procedures (already underwent surgical procedure, 9 [45.0%] vs 10 [50.0%]). The initial mean (SD) m-YPAS scores were 37.3 (21.7) and 37.1 (13.8) for the experimental and control groups, respectively; the mean (SD) m-YPAS scores when entering the OR were 33.0 (18.4) and 48.6 (15.9), respectively (P = .009). The mean (SD) difference between the m-YPAS score at the first and second measurements of each participant was −2.8 (7.2) in the experimental group and 10.7 (10.8) in the control group. The 13.5-point difference between these averages was statistically significant (P = .003).

CONCLUSIONS AND RELEVANCE The app was effective in reducing preoperative anxiety in Italian children admitted to an Italian National Health System pediatric hospital and may act as a substitute for staff-provided interventions, allowing possible reductions of hospital costs.

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Preoperative anxiety (PA) is of utmost concern in pediatrics; 40% to 60% of children undergoing surgical procedures experience high levels of PA.[1,2] Preoperative anxiety may have negative effects on children, such as higher postoperative pain,[3] emergence delirium,[4] uncooperative behavior, and higher doses of sedation or preoperative analgesia.[5] Typical PA signs are increased muscle tone, sleep disturbances, a cessation of playing, agitation, and escape behavior.[6] In children younger than 6 years, PA is expressed through the fear of separation from the mother and the terror of the unknown, while the fear of death and mutilation are prevalent in older children.[6]

One category of interventions effective in reducing PA is to provide preprocedure information to children in a manner that is appropriate for their developmental stage[6-12]; studies show that most children who undergo a surgical procedure wish to receive detailed information on what they will encounter and on what will happen in the operating room (OR).[13] The preprocedure information helps to reduce fear of the unknown and to increase the sense of control for the child,[6,8] and it is also a fundamental right.[14] An effective method for giving children information is the guided tour of the OR prior to an elective surgical intervention, currently used in various pediatric hospitals (PHs).[15-18]

Even the use of clowns in PHs is an effective method for reducing PA in children. To date, 4 randomized clinical trials, which included 257 children aged up to 12 years, have evaluated the effectiveness of interventions involving clowns vs routine care for reducing PA levels.[19-22] The arm sizes varied from 20 to 52 children. All studies[19-22] measured PA with the modified Yale Preoperative Anxiety Scale (m-YPAS).[23] Preoperative anxiety was always significantly lower in children receiving the clown intervention. Four quasiexperimental studies show similar results.[24-27]

However, the implementation of these interventions may be difficult because of organizational and financial limits. Accompanying a child for a guided tour of the OR is time-consuming, and nurses may not be available owing to high workloads of care. Even the use of clowns can be difficult because their costs may not be affordable for some PHs and because health care staff sometimes do not like to work with clowns.[19]

The use of new information technology devices (NITDs) may help to overcome the obstacles to the implementation of these methods in clinical practice. New information technology devices are easy to use and cost-effective and can be used virtually at any time and place.[28] These devices have already been effectively introduced in PHs to reduce distress in children.[29-31] Several NITDs (eg, personal computers,[32,33] video glasses,[34] streaming videoplayers,[35] MP3 players, iPods,[36] smartphones,[37,38] and handheld video games[39]) have been used easily and effectively in the preoperative period as a vehicle for multimedia content (eg, cartoons, video games, video clips, television broadcasts, and virtual reality) to reduce children's PA through distraction.

Providing 2 methods that are effective at reducing PA for children (a guided tour of the OR and clown physicians) through an NITD might reduce costs and make such methods available cheaply and for understaffed PHs. However, one cannot assume that methods that work in vivo are effective even through an NITD. Therefore, a study is necessary to evaluate the effectiveness of providing these interventions to children using NITDs.

The purpose of the study was to evaluate the effectiveness of a new method that provides preprocedure information through a tour of the OR led in a funny way by clown physicians and that is administered to children through an NITD. We hypothesized that this method would reduce PA compared with routine care in school-aged children who underwent elective surgical procedures.

Key Points

Question What is the effectiveness of an app that combines a tour of the operating room and clown physicians, for reducing preoperative anxiety in children?

Findings This randomized clinical trial found that the app resulted in lower levels of preoperative anxiety (measured by the modified Yale Preoperative Anxiety Scale) in 20 children aged 6 to 11 years undergoing elective surgery compared with 20 similar controls. The experimental group had a decrease of anxiety from baseline compared with an increase from baseline in the control group.

Meaning The app is a low-cost, easy-to-use, effective method to reduce preoperative anxiety in children undergoing surgical procedures.

Methods

This study was an unblinded randomized clinical trial with parallel groups with a 1:1 allocation ratio. We compared the effectiveness of an informative preprocedure intervention led in a funny way by clown physicians and administered to children on NITDs prior to an elective surgical procedure against the standard intervention in reducing PA in school-aged children. Preliminarily, a 6-minute video (**Video**) was produced in collaboration with the association Soccorso Clown (Clown Rescue), a professional association that provides the service of clown physicians to the Meyer Children's Hospital (MCH) in Florence, Italy, for animation and children's entertainment. In this video, 2 clown physicians (Dr Cloud and Dr Wisp) take a tour of one of the ORs at MCH. During the tour, they make jokes and perform gags, explaining to each other in a playful and funny—although technically correct—way what an OR is like and the objects and situations that can be found there (eg, the operating table, the anesthesia mask, the saturimeter probe, the electrocardiogram electrodes, the cardiac monitor, and the thermo-blanket). The screenplay was prepared by a group of expert nurses and psychologists. The video was named Clickamico (Buddyclick). The 2 clown physicians are professional actors who are specifically trained to work in PHs. The video in Italian with English subtitles is available at http://archpedi.jamanetwork.com/multimediaPlayer.aspx?mediaid=13022104. The video was then turned into an app for mobile devices.

The experimental intervention under study consisted of the administration of the app to the experimental group. Every aspect of the nursing and medical care provided to children during the study was compliant with the hospital's protocols, which were not modified based on participants' study groups. For each afternoon shift, only 1 child participated in the study to avoid participants included in the study influencing or being influenced by other recruited participants. However, it was impossible to avoid participants in the control group being influenced by other children who were not participating in the study who received the same standard informative intervention. The study was approved by the ethics committee of the Meyer Children's Hospital in Florence. The full study protocol can be found in the Supplement. Written informed consent was provided by parents/guardians.

Population

Children begin to understand humor at 6 to 7 years of age.[40] While younger children show their delight at the creativity of physical expression,[41] which is typical of clowns, teenagers are much less receptive to this kind of humor and may feel more embarrassment[42] for the childish aspects of clown acting. Therefore, in accordance with other studies on clown physicians,[19-22] we decided to limit the participation in the study to children in primary school.

The study population consisted of children hospitalized at MCH who were aged 6 to 11 years, were not diagnosed as having cognitive deficits or cognitive and intellectual developmental delay, had a surgical intervention (eg, phimosis, abdominal hernia, or orthopedic corrections) scheduled for the next day, were admitted in the afternoon before the surgical procedure, and were native Italian speakers whose parents were both native Italian speakers.

Children were excluded if they were older than 11 years or younger than 6 years, were diagnosed as having cognitive deficits or cognitive and intellectual developmental delay, were not admitted in the afternoon before the surgical procedure, were not native Italian speakers, or whose parents were not both native Italian speakers.

Experimental Intervention

The experimental intervention consisted of the administration of the video. The afternoon before the surgical procedure, after obtaining informed consent, nurses showed the video on a tablet to each child in the experimental group in the presence of their accompanying parent/guardian. Once the video ended, nurses asked each child and accompanying parent/guardian if they had any questions about the surgical procedure; if so, nurses answered them to the best of their knowledge, as stated by the hospital protocols. The child was free to interrupt the video at any time. Children who decided to stop watching the video or who, after asking a question, did not listen to the whole or part of the answer were considered as dropouts and were excluded from the study. When recruited children were not in a single-bed room, they were moved to a separate empty room to watch the video so that no other children or accompanying persons were present in order to exclude possible external interruptions or interferences. After watching the video, children and accompanying persons were free to communicate with others.

Control Intervention

The control intervention consisted of the standard informative intervention regarding the surgical procedure of the next day. The afternoon before the surgical procedure, after obtaining informed consent, nurses asked each child and their accompanying parent/guardian if they had any questions regarding the procedure; if so, nurses answered them to the best of their knowledge, as stated by the hospital protocols. Children who, after asking a question, did not listen to the answer in whole or in part were excluded from the study. When recruited children were not in a single-bed room, they were moved to a separate empty room to avoid interruptions and interferences. After asking the nurse questions and listening to the answers, children and accompanying persons were free to communicate with others.

Outcome and Measure

The outcome measured in the study is represented by PA in the child and was measured using m-YPAS.[23] The m-YPAS is an observational scale including 5 categories of child behavior, including activity (score range, 1-4), vocalizations (score range, 1-6), emotional expressivity (score range, 1-4), state of apparent arousal (score range, 1-4), and use of parents (score range, 1-4). These categories are weighted differently, and the overall score is calculated so that the range of the total score for each child varies from 23.33 (minimum anxiety) to 100 (maximum anxiety).

The m-YPAS evaluation was performed on each child at 2 times: the afternoon before the surgical procedure, immediately before the administration of the study intervention, and the day of the procedure when the child was placed on the stretcher that transferred the child from bed to the OR. Because no validated Italian version of the m-YPAS exists, the scale was used in its original English form. The m-YPAS evaluation was performed alternatively by 3 English-proficient investigators who had been trained on the correct use of m-YPAS. The 3 raters delivered their observation records to the research group after collection. During the collection of data, they had no contact with members of the research group.

Setting

The study took place in 2 inpatient wards of MCH for a period of 9 months (December 2013 to September 2014).

Recruitment

Participation in the study was anonymous and voluntary. Parents/guardians present at their children's bedside were approached if the child met all inclusion requirements and was hospitalized in 1 of the 2 designated wards during the afternoon shift (1 PM to 8 PM) of 1 of the 5 nursing rosters, ie, once every 5 days. The afternoon before the procedure, nurses informed the parents/guardians and children about the study and answered their questions. Those who agreed to participate signed a form of written consent for their children. Children were encouraged to speak their opinion about participation in

Table. Differences Between the Study Groups

Characteristic	Experimental Group (n = 20)	Control Group (n = 20)
Age, mean (SD), y	8.8 (2.5)	8.6 (2.2)
Age of parents, mean (SD), y	41.8 (6.2)	41.3 (5.0)
Female, No. (%)	11 (55.0)	9 (45.0)
Already underwent a surgical procedure, No. (%)	9 (45.0)	10 (50.0)
Modified Yale Preoperative Anxiety Scale score, mean (SD)	37.3 (21.7)	37.1 (13.8)

the study. Recruitment was not performed on Fridays and Saturdays because elective surgical procedures were not performed on Saturdays and Sundays. In the event that more than 1 child was present at the time of recruitment, the child who participated in the study was selected by randomly drawing from a bag where the names of those children were written on pieces of paper.

Randomization

The patients were assigned to groups by randomization. Twenty nontransparent envelopes containing a card with the words *experimental group* as well as 20 envelopes containing a card with the words *control group* were placed in a box in order to have the total number of envelopes equal the number of children to be recruited, with equal chance for the participants to be included in either group. At time of inclusion, an envelope was drawn from the box, and the child was assigned to the group written within the envelope.

Four more nontransparent envelopes were put in a second box, 2 of which contained a card with the words *experimental group* and the other 2 containing a card with the words *control group*. This second box would have been used in the event that any of the children recruited were withdrawn from the study. In this case, if the 40 initial envelopes were finished, other children would have drawn from the second box until 20 children were recruited in both groups.

Sample Size

The 4 randomized clinical trials[19-22] in which the m-YPAS was used to evaluate clowns' effectiveness at reducing PA in children found m-YPAS score differences between the experimental and control groups ranging from 10 points[20] to 30.75 points.[19] To determine the sample size of our study, we considered the m-YPAS score difference found in 2 of the 4 studies[20,21] (that is, 10 m-YPAS points) as the minimum clinically significant reduction of PA. Based on this expected difference and hypothesizing a pooled SD slightly higher than the former, a sample size of 40 children was determined.

Statistical Analysis

For each group, we calculated mean age, relative frequency of sexes, relative frequency of children who had previously underwent surgical procedures, mean age of parents, mean m-YPAS score at initial measurement, mean m-YPAS score at the second measurement, and mean of the differences between the first and second m-YPAS scores of each child (**Table**). The differences between the means were tested with an analysis of variance, and the differences between the relative frequencies were tested using the χ^2 test. Significance was set at $P < .05$. The test power was also calculated (null hypothesis accepted for $1-\beta < 0.8$).

Results

Forty children participated in the study, of which 20 were assigned to the experimental group and 20 to the control group. One child initially recruited and assigned to the control group was excluded from the study because the surgical intervention was cancelled. The mean [SD] age of the children was 8.7 [6.5] years and was 41.6 [5.5] years for the accompanying person. Half of the children (50%) were female, and 19 (47.5%) had undergone a previous surgical procedure. The Table shows the differences between the children in the 2 groups. Because the differences were not statistically significant, the 2 groups can be considered to be homogenous with regard to all the considered variables.

The mean m-YPAS scores of PA at the initial test did not differ significantly between the 2 groups. At second measurement, the mean (SD) m-YPAS score for the experimental group was 33.0 (18.4), whereas the mean (SD) score in the control group was 48.6 (15.9). The 15.6-point difference between the means was statistically significant ($P = .009$; test power, 80.7%). The mean (SD) difference between the m-YPAS score at the first and second measurements was −2.8 (7.2) in the experimental group and 10.7 (10.8) in the control group. The 13.5-point difference between these averages was also statistically significant ($P = .003$; test power, 93.0%).

Discussion

To our knowledge, this is the first study that assessed the effectiveness of an intervention of clown physicians combined with a tour of the OR administered by means of an NITD. With this experimental study, we wanted to test the effectiveness of a new method to reduce PA in children, which combines the effectiveness of the intervention of clown physicians[19-22] and of preprocedure information through a guided tour of the OR[15-18] and which is administered to children through an NITD. If effective, this method would help to reduce PA in children, even in those PHs with reduced staff and economic resources, and would allow a higher number of children to receive effective nonpharmacological interventions to reduce PA. Nonpharmacological interventions improve children's cooperation[43] and contribute to containing health costs,[44,45] as they are usually cheaper than medications. Also, some nonpharmacological interventions are as effective as drugs in reducing PA[22]; therefore, their use may help to avoid the adverse effects of some medications.

This study showed that children who received the intervention had significantly lower mean values of PA than control children before entering the OR, although their initial mean values of PA were nearly identical. Because the 2 study groups

did not differ significantly with respect to other relevant variables, such as age, sex, age of parents, and previous surgical procedure, the lower PA observed in the experimental group can be attributed to the app. However, the app has been shown to be effective only prior to elective surgical interventions. Therefore, it cannot be recommended in children undergoing emergency surgical procedures. Also, the app is in Italian and was administered to Italian children; it is not advisable to use for non-Italian children until the method is assessed and validated in other languages. Finally, it has not been tested in comparison or in association with any anxiolytic drug.

Our study had a number of limitations. A limitation of the study may be its sample size, although it is similar to that of the other randomized clinical trials regarding clowns' effectiveness on PA,[19-22] and power analysis gives values higher than 0.8. It was not possible to stratify data according to age, sex, or previous surgical procedure. Further studies may confirm our results and provide additional information.

Conclusions

The Clickamico app proved effective in reducing PA in children who were native speakers of Italian undergoing elective surgical procedures. Further studies are needed to evaluate its possible effectiveness in other contexts, after an appropriate linguistic and cultural validation, and to evaluate it compared with and in association with anxiolytic drugs. The app may represent a low-cost, easy-to-use tool to reduce PA in children, even in those PHs in which there is no staff to implement nonpharmacological methods for reducing children PA.

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Study concept and design: Liguori, Stacchini, Ciofi, Festini.
Acquisition, analysis, or interpretation of data: Olivini, Bisogni, Festini.
Drafting of the manuscript: Ciofi, Olivini, Festini.
Critical revision of the manuscript for important intellectual content: Liguori, Stacchini, Bisogni, Festini.
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