

Parental Anxiety During Children's Surgery: The Effect of Preoperative Cognitive Behavioral Program

Preethy Dsouza¹, Aparna Bhaduri², Anice George³, RenuG⁴, Ashley D'Cru⁵

1 Research Scholar ,Manipal College of Nursing, Manipal University

2 Former Professor, Manipal College of Nursing, Manipal University

3 Dean, Manipal College of Nursing, Manipal University

4 Lecturer, Sultan Qaboos University, Oman

5 Director and Senior Pediatric Surgeon at NH Multispecialty Hospital, Bangalore

preethysouzaa@gmail.com, aparna_1935@yahoo.com, anicejain@yahoo.co.in, renug5@yahoo.co.in

ABSTRACT:

Hospitalization and surgery are very stressful and traumatic events for both children and their families. The research focuses on developing and evaluating preoperative cognitive behavioral program in reducing the anxiety of parents of children undergoing surgery. The quasi experimental design used purposive sampling in which 20 parents were allotted to the control group and 20 parents to the experimental group. Results showed that preoperative cognitive behavioral program was effective in decreasing parental anxiety.

KEYWORDS: Anxiety, Parents, Cognitive Behavior, Surgery, Preoperative

INTRODUCTION

When a child requires surgery, the stress is borne by the child's entire family. Anxiety in the preoperative period is increased unnecessarily by misinformation and often exaggerated preconceived notions acquired from the society. It must be remembered that what may be routine to the health care providers is often frightening to parents. Addressing parental concerns, providing factual information, and allaying parental anxieties are essential in the preoperative preparation of children. Preoperative anxiety is associated with a number of poor postoperative outcomes and with significant parental and child distress before surgery [1]. Adequate parental preparation alone may be sufficient to reduce anxiety in children [2]. Accordingly, preoperative preparation providing specific and appropriate information to prepare children and parents for surgery is warranted, as caregivers are frequently unfamiliar with the operative routine [3- 6].

AIM

The aim of the research is to examine the effectiveness of preoperative cognitive behavioral program in reducing the anxiety of parents of children undergoing surgery.

REVIEW OF LITERATURE

Franck & Spencer critically analyzed the published research literature on providing information about children's anesthesia to parents [7]. The intervention studies tested different methods of providing information, including verbal, video or written modalities and showed some improvements in knowledge, anxiety and satisfaction. Parents want detailed information about the specifics of anesthetics procedures, risks, and personnel roles and this information should be incorporated into the routine pre-surgical anesthesia assessment clinic visits. In addition, Bevan, Johnston, Tousignant, Kirnon and Carranza stated that preoperative parental anxiety levels correlated with the child's fears and behaviour one week after surgery [8]. Further, Bellew, Atkinson, Dixon & Yates concluded that anxiety can

be transmitted to the child and may have negative implications not only at the time of operation but also after surgery and hospitalization [9]. Besides, it was identified that 32% of the patients could be considered as "anxiety cases" and over 80% of patients have a positive attitude toward receiving information [10]. Supplemental preoperative preparation programs have demonstrated a reduction in anxiety for the parent [11 - 14]. Preoperative anxiolysis for parents is important because parental anxiety has been identified as a risk factor for preoperative anxiety and postoperative maladaptive behavior in children [8,10,15]. The need for information and anxiety are not independent factors in the preoperative phase. A positive relationship has been demonstrated between preoperative anxiety and the need for information [10]. Research has shown that parents who participate in a preparation program or who view a preoperative video regarding anesthesia demonstrate reduced preoperative anxiety on the day of surgery. Kain and colleagues compared three types of behavioral preoperative preparation programs including a tour of the operating room (information based), a commercially available videotape (modeling based), or a Child Life preparation (coping based) with 75 children aged 2 to 12 years. Children and parents who received Child Life coping skills preparation exhibited less anxiety immediately following the preparation in the holding area on the day of surgery and on separation to the operating room than children and parents who did not receive this preparation [16]. An earlier research demonstrated that parents who underwent extensive psychological preparation reported significantly greater satisfaction and less anxiety than parents of the other groups [11]. Various research studies indicated that the use of videotape has gained more attention recently as a supplemental mode of education as they facilitate information provision, are possibly anxiolytic, and are less costly [1,12,17]. Effectiveness of preoperative video in reducing anxiety in parents was recorded. Ellerton and Merriam found that preoperative video seems to be beneficial [2]. Karl described the preoperative use of a videotape that illustrates the induction of anesthesia and offers

information, including a discussion of pediatric anesthesia risks [13]. Parents considered certain aspects of the videotape helpful, although only those bringing a child to surgery for the first time exhibited a demonstrable reduction in concerns about anesthesia. A randomized controlled trial by Cassidy, Wysocki, Miller, Cancel, and Izenberg recognized the use of a preoperative informational video as a useful modality for parental anxiety reduction [17]. Further, McEwen, Moorthy, Quantock, Rose, and Kavanagh corroborated these findings and also advocated the use of a preoperative informational video for parents as a useful intervention for reducing anxiety [18].

Besides video, other types of psycho educational interventions have been found beneficial in preparation for surgery. William Li, Lopez, Isabel Lee in 2006 examined the effects of therapeutic play intervention on outcomes of children undergoing day surgery, and the involvement of parents in the psycho educational preparation of children for surgery. By using a simple complete randomization method, 97 of children with their parents were assigned to the experimental group receiving therapeutic play intervention, and 106 children with their parents were assigned to the control group receiving routine information preparation. The results showed that both children and their parents in the experimental group reported lower state anxiety scores in pre- and post-operative period [19].

METHODOLOGY

RESEARCH QUESTION

Is preoperative cognitive behavioural program effective in reducing anxiety in parents of children undergoing surgery?

RESEARCH DESIGN

This research design used was a quasi-experimental design with purposive sampling. The intervention; preoperative cognitive behavioral program was applied exclusively to the experimental group. The control group had routine information.

SETTING

The study was conducted in the pediatric surgery department of St. Johns Medical College Hospital, Bangalore, India; a thousand-bedded tertiary referral hospital. The pediatric surgery general ward consisted of 25 beds with an operation theatre attached to the ward. The department conducts about 900 to 1000 operations annually.

PARTICIPANTS

Participants in this study included 40 parents of children undergoing major elective surgery in a super specialty hospital with one of the largest populations of pediatric surgery patients in Karnataka, India. For inclusion in the study, parents met the following criteria; (a) having a child of 5-14 years undergoing major elective surgery, and (b) child being hospitalized for one week after surgery. Parents of children who are

critically ill and those who were not available were excluded from the study. After assessing the eligibility parents were randomly allocated to experimental and control group. The number of parents who met the study criteria was 40; 20 in the experimental group and 20 in the control group. There were no statistically significant differences between the parents of experimental and control group in terms of background characteristics.

DESCRIPTION OF PROCEDURES FOR PROTECTION OF PARTICIPANTS' RIGHTS

The study was approved by the research and ethics committee of the institution. Written consent was taken from the participants prior to administration of the questionnaires. Questionnaires were coded and confidentiality was maintained at every stage of research.

INTERVENTION

PREOPERATIVE COGNITIVE BEHAVIOURAL PROGRAM

It included educative video, hospital tour and interactive sessions. The video covers the preoperative, intra operative and postoperative period of children undergoing surgery. It emphasized how to provide care before, during and after surgery and parental guidance. In addition general information about surgery and anesthesia was also given. The video was in a story form and had real life situations which were educational for parents and children. The film was developed by reviewing related literature, discussion with experts and incorporating the real life situation of children undergoing surgery and their parents. The objectives of the video session were identified and the outline of the content areas prepared. Further, content validity was established by fourteen experts in the field of psychology, pediatric nursing and pediatric surgery. The video film developed in English and in the regional language, Kannada, was also validated by fourteen experts and twenty parents (target audience). The Video film was developed by the research team with input from technical experts as well. Besides the video film, hospital tour was included. Hospital tour focus on the areas children and their parents need to be familiar during hospitalization such as pediatric surgery ward, operation theatre, recovery room, waiting area and post-operative unit. Interactive sessions were planned following viewing video and hospital tour. Parents were given opportunity to clarify their doubts and to interact with doctors, nurses and other health professionals involved in the care of children undergoing surgery. The control group received routine preparation which included explanation about surgery, pre-operative and post-operative period by doctors and nurses.

DATA COLLECTION PROCEDURE

The study was approved by the institutional ethical review board. Prior to full implementation of the study, all procedures were pilot-tested with ten parents, with

no difficulties encountered. Parents were selected based on the inclusion criteria and the researcher informed the parents about the research project and obtained their consent.

DESCRIPTION OF INSTRUMENTS, INCLUDING MEASUREMENT RELIABILITY AND VALIDITY EVIDENCE

TOOL-I: PERFORMA ON BACKGROUND DATA

The Performa included items on background data of participating parents. The items were open ended, which were elicited by interviewing parents. The background data of the parents included gender, age, education, occupation, and previous hospital related experience.

TOOL-II: STATE TRAIT ANXIETY INVENTORY (STAI)

The STAI is a widely used self-report anxiety assessment instrument. More than 1000 studies using the STAI have been published in peer-reviewed literature. The questionnaire contained two separate sections with 20-items in each section. It was a self-report rating scale for measuring trait and state anxiety. Subjects responded on a four-point scale, total scores for situational and base line questions separately ranged from 20-80 with higher scores denoting higher levels of anxiety (e.g. a parent was defined as very anxious when the STAI state sub scale score was in the upper quartile), as quoted by Kain et al (1998). Test-retest correlation's for STAI are high (0.73–0.86). The construct validity value ranged from 0.83 to 0.94, which suggested very good construct validity. As it was a standardized tool, the researcher did not repeat the validity and reliability testing. Pre testing was done to determine the clarity, feasibility and time taken to complete it. Time taken by each subject to complete

State Trait Anxiety Inventory varied from 20-40 minutes.

ANALYSIS AND INTERPRETATION

Chi-square values in the Table-1 show that there is no significant difference between the experimental and the control group parents in relation to gender, occupation, hospital experience, education and income.

The *t* values in Table-2 showed that none of the mean values were significantly different between the experimental and the control group parents with regard to age and family size. Thus, it is inferred that the parents are drawn from the same population with regard to the characteristic of age, gender, occupation, hospital experience, education, income, and family size as shown in Table-1 and 2.

ANXIETY SCORES OF PARENTS OF THE EXPERIMENTAL AND THE CONTROL GROUP

Data related to the anxiety of the parents are generated through the use of parental anxiety inventory. The pre anxiety and post anxiety scores are analyzed and shown in the Table 3. From the data in the Table-3, it was evident that the 45% of pre anxiety scores of control groups were between the class interval of 91-110, whereas it was between 111-130 for the 50% of experimental group. Post anxiety scores of control group were similar to the pre anxiety scores. But majority (75%) of post anxiety scores of the experimental group were in the class interval of 31-50 indicating an apparent reduction in anxiety in the parents of the experimental group.

Comparison of pre intervention anxiety mean of Parental anxiety Scores of the control and the experimental group parents

Thus, it is concluded that the intervention was effective in reducing the anxiety of the experimental group parents.

Table -1. BACKGROUND DATA OF THE PARENTS

	Control Group (f)	Experimental Group (f)	Chi-square (df=1)
1. Gender			
1.1 Male	11	9	$\chi^2=0.40,$ $p=0.53$
1.2 Female	9	11	
2. Occupation			
2.1 Unskilled	11	8	$\chi^2=0.96,$ $p=0.62$
2.2 Semiskilled	5	6	
2.3 Skilled	4	6	
3. Previous Hospital experience			
3.1 Yes	9	10	$\chi^2=0.10,$ $p=0.75$
3.2 No	11	10	
4. Parental education			
4.1 > Median	7	13	$\chi^2=2.50,$ $p=0.11$
4.2 < Median	13	7	
5. Income			
5.1 > Median	9	6	$\chi^2=0.43,$ $p=0.51$
5.2 < Median	11	14	

Chi-square values in the Table-1 shows that there is no significant difference between the experimental and the control group parents in relation to gender, occupation, hospital experience, education and income. Some of these baseline variables if different between the experimental and control

group would have affected the study findings. The table data indicates that the two groups were similar at the start of the study which enhances the validity of the findings.

Table-2. Range, Mean, SD and ‘t’ Values Showing the Comparison of the Experimental and the Control Group Parents in Relation to Age and Family Size

	Control Group (n=20)			Experimental Group (n=20)			t Value
	Range	Mean	SD	Range	Mean	SD	
Parental age	28-45	35.5	4.9	28-45	34.7	5.1	t=0.50, df=38 p=0.62
Family size	4-6	5.0	0.8	4-6	5.1	0.8	t=0.20, df=38, p=0.84

The *t* values in Table-2 showed that none of the mean values were significantly different between the experimental and the control group parents with regard to age and family size. As the parents of the control and experimental group belong to similar age group, the understanding about the educational intervention could be in a similar way. Thus, it is inferred that the parents are drawn from the same population with regard to the characteristic of age, gender, occupation, hospital experience, education, income, and family size as shown in Table-1 and 2.

Table-3. Percentage and frequency distribution of pre and post anxiety scores of experimental and control group parents

Scores	Control Group (n=20)							
	Pre-anxiety				Post-anxiety			
	f	%	cf	cf%	f	%	cf	cf%
31-50	-	-	-	-	-	-	-	-
51-70	-	-	-	-	-	-	-	-
71-90	3	15	3	15	1	5	1	5
91-110	9	45	12	60	10	50	11	55
111-130	6	30	18	90	7	35	18	90
131-150	2	10	20	100	2	10	20	100

Scores	Experimental Group (n=20)							
	Pre-anxiety				Post-anxiety			
	f	%	cf	cf%	f	%	cf	cf%
31-50	-	-	-	-	15	75	15	75
51-70	-	-	-	-	5	25	20	100
71-90	2	10	2	10	-	-	-	-
91-110	6	30	8	40	-	-	-	-
111-130	10	50	18	90	-	-	-	-
131-150	2	10	20	100	-	-	-	-

From the data in the Table-3, it was evident that the 45% of pre anxiety scores of control groups were between the class interval of 91-110, whereas it was between 111-130 for the 50% of experimental group. Post anxiety scores of control group were similar to the pre anxiety scores. But majority (75%) of post anxiety scores of the experimental group was in the class interval of 31-50 indicating an apparent reduction in anxiety in the parents of the experimental group. The distribution pattern of anxiety scores clearly indicate that the intervention did work for the experimental group.

Table-4. Range, Mean, SD, t values of pre anxiety scores of the experimental and the control group

	Control Group (n=20)			Experimental Group (n=20)			t Value (df=38)
	Range	Mean	SD	Range	Mean	SD	
State anxiety	32-70	56.1	11.5	38-71	58.0	9.2	t=0.59, p=0.56
Trait anxiety	36-70	52.8	9.3	45-70	57.2	6.6	t=1.72, p=0.09
Overall anxiety	70-138	108.8	19.1	83-140	115.2	15.2	t=1.16, p=0.25

The t value computed between the two groups as shown in the Table-4 indicates no significant difference in the pre-anxiety scores. It implies that groups were similar at the baseline anxiety. It is essential to know the pre-anxiety scores to find the effectiveness of intervention. If the groups were different at baseline, it would have been a major confounding variable affecting the study results.

Table-5. Range, Mean, SD and t values of post anxiety scores of the experimental and the control group

Area	Control Group (n=20)			Experimental Group (n=20)			t Value (df=38)
	Range	Mean	SD	Range	Mean	SD	
State anxiety	39-68	55.4	9.2	20-32	24.4	3.9	$t=151.19^*$ $p<0.001$
Trait anxiety	36-66	53.3	7.7	20-30	23.0	2.4	$t=328.67^*$ $<p=0.001$
Overall anxiety	75-131	108.7	14.6	40-62	47.3	5.5	$t=277.64^*$ $p<0.001$

* Significant

The t values presented in Table-5 shows that the overall means of post-test of the control group (108.7) and the experimental group (47.3) is statistically significant, $t_{(38)}=277.64$, $p<0.001$. Moreover, the significance is at 0.001 levels which shows that the intervention is highly effective. Thus, it is concluded that the intervention was effective in reducing the anxiety of the experimental group parents.

DISCUSSION

Majority of the parents in the experimental group (55%) were mothers and in the control group (55%) were fathers. Around 65% of the parents in both the groups were between 31-40 years. Maximum number of parents in the experimental group (35%) was high school educated and 45% of the control group were middle school educated. Maximum number of parents in the experimental group (40%) and the control group (55%) were unskilled workers. Maximum number of parents in the experimental group (55) had family income between 5,000-10,000/- whereas, 45% in the control group had more than 10,000/-. Nearly half the parents of the experimental and the control group had previous hospital related experience.

Preoperative anxiolysis for parents is important because parental anxiety has been identified as a risk factor for preoperative anxiety and postoperative maladaptive behavior in children [8,10,15]. The current research demonstrates that preoperative preparation program in parents resulted in anxiolysis for parents of pediatric surgery patients. Supplemental preoperative preparation programs have demonstrated a reduction in anxiety for the parent [11-14,16,19]. The main component of the preoperative preparation of the current study was the video film. Previous research indicated that the use of videotape has gained more attention recently as a supplemental mode of education as they facilitate information provision, are possibly anxiolytic, and are less costly [12,14,17]. Effectiveness of preoperative video in reducing anxiety in parents was recorded [2]. Moreover, McEwen, Moorthy, Quantock, Rose, and Kavanagh advocated the use of a preoperative informational video for parents as a useful intervention for reducing anxiety [18].

Although majority of studies reported consistent results with the current study, there are few studies reported that parents who were prepared for children's

surgery did not show a statistically significant reduction in anxiety scores ^{2,9}. However, Kain, Caramico, Mayes, Genevro, Bornstein and Hofstadter reported that parents who received extensive preparation reported that they were significantly less anxious in the preoperative holding area on the day of surgery compared with parents in the minimal preparation groups ($p=0.47$) [16]. In the current study, psycho educative preparation included video film, OR tour and discussion session which was a detailed preparation program.

Although this study confirms the parental anxiolytic due to intervention, its design has few limitations. A possible limitation of this study is the videotape itself. Previous studies assessing the benefits of preoperative preparation videotapes have rarely described the setting for filming of the videotape. The videotape used in this study was produced in our institution's surgical facilities. Participating parents had not previously experienced this setting. We do not know whether the same anxiolytic and educational benefits found in our institution would be recognized in another institution. Furthermore, in the present study, anxiety was not assessed subsequently during the postoperative period. Therefore, whether the anxiolytic effects of the videotape were sustained throughout the perioperative period was not evaluated.

Future studies should also take into account the cost and benefits of supplemental preparation programs. The planning and production of a high-quality videotape may cost a lot depending on the use of professional producers and actors and the time expended. Additional parental measures, such as compliance with preoperative instructions (specifically nothing by mouth instructions) and informed consent, should also be evaluated because facilitation of either of these measures may result in additional cost-savings.

In summary, in this study, it is demonstrated that a preoperative cognitive behavioural program can significantly reduce parental anxiety before surgery of their children.

IMPLICATION NURSING PRACTICE

Preparing children undergoing surgery and their parents is an important responsibility for paediatric nurses. Nurses working in the paediatric surgery units are faced with the challenges of preparing children and parents for surgery. As it was a video film addressing issues in the preoperative, intraoperative and postoperative period, it could be used in the hospitals to prepare children and their parents during the preoperative period. It was made as a documentary film which gave general information of the preoperative, intraoperative and postoperative period which could be used for any type of surgical procedure. As the children and parents would be satisfied with the type of programme, the nurses could achieve personal satisfaction in their work. The film would help nurses get better cooperation and participation from parents and children. As parental anxiety negatively affect how the child deals with the surgical process, paediatric facilities should take necessary steps to handle parental anxiety. Once we put a system of handling parental anxiety, it will have a great impact in providing family centered care.

CONTRIBUTION BY AUTHORS

The particular research work was carried out after obtaining ethical clearance and all the necessary permissions from the institution where the data has been collected. Hence, there is no need to have a no objection certificate. The first author had undertaken the research as a part of her MPhil Nursing program at Manipal University. During that time she was working as a teaching faculty at St.John's Medical College Hospital, Bangalore. The second author was the guide who was then working as a professor at Manipal University and the fifth author was the co-guide for the research who was then the consultant surgeon at St.Johns Medical College Hospital. Third and fourth authors participated in preparing the manuscript for publication.

REFERENCES

1. Kain, Z.N; Caldwell, A (2005) Preoperative psychological preparation of the child for surgery. *AnesthesiolClin North Am*, 23(4): 597-614.
2. Ellerten, M.L; Merriam, C. (1994) Preparing children and families psychologically for day surgery. *J AdvNurs*, 19(6): 1057-1062.
3. Brewer S; Gleditsch S.L; Syblik D, Tietjens M.E, Vacik H.W (2006) Pediatric anxiety: child life intervention in day surgery. *J PediatrNurs*, 21(2): 13-22.
4. Edwinston, M., Arnbjornsson, E., & Ekman, R. (1988) Psychologic preparation program for children

- undergoing acute appendectomy. *Pediatrics*, 82(1), 30-36.
5. Lynch, M. (1994) Preparing children for day surgery. *Child Health Care*, 23(2), 75-85.
6. Rawlinson S. C, & Short J. A (2007) The representation of anaesthesia in children's literature. *Anaesthesia*, 62: 1033-1038.
7. Franck, L.S; Spencer, C (2005) Informing parents about anesthesia for children's surgery: a critical literature review, *Patient EducCouns*, 59(2):117-25.
8. Bevan, J. C., Johnston, C., Haig, M. J., Tousignant, G., Lucy, S., Kirmon, V., et al. (1990) Preoperative parental anxiety predicts behavioural and emotional responses to induction of anaesthesia in children. *Can J Anaesth*, 37(2), 177-182.
9. Bellew M, Atkinson KR, Dixon G, Yates A (2002). The introduction of a pediatric anesthesia information leaflet: an audit of its impact on parental anxiety and satisfaction. *Pediatr anaesth*,12(2):124-30.
10. Moerman, N.; Frits, S.A.M.; Muller, J.M. and Oosting, H. (1996). The Amsterdam preoperative anxiety and information scale. *AnaesthAnalg*, 82: 445-451.
11. Visintainer, M.A. and Wolfer, J.A. (1975). Psychological preparation for surgical pediatric patients. *Paediatrics*, 56(2): 181-201.
12. Pinto, R.P; Hollandsworth JG Jr (1989) Using videotape modeling to prepare children psychologically for surgery: influence of parents and costs versus benefits of providing preparation services. *Health Psychol*, 8(1): 79-95.
13. Karl HW, Rosenberger JL, Larach MG, Ruffle JM (1993) Transmucosal administration of midazolam for premedication of pediatric patients-comparison of the nasal and sublingual routes. *Anesthesiology*, 78:885-91.
14. Caldwell-Andrews, A.A., Kain, Z.N., Mayes, L.C., Kerns, R.D., & Ng, D. (2005) Motivation and maternal presence during induction of anesthesia. *Anesthesiology*, 103, 478-483.
15. Kain, Z.N.; Wang, S.; Caramico, L.A.; Hofstadter, M. and Mayes, L.C. (1996). Parental desire for perioperative information and informed consent. *Anaesthanalg*, 84: 299-306.
16. Kain, Z.N.; Caramico, L.A.; Mayes, L.C.; Genevro, L.J.; Bornstein, M.H. and Hofstadter, M.B. (1998). Preoperative preparation programs in children. *AnaesthAnalg*, 87: 1249-1255.
17. Cassady, J.F.; Wysocki, T.T.; Miller, K.M.; Cancel, D.D. and Izenberg, N. (1999). Use of preanaesthetic video for facilitation of parental education and anxiety reduction before pediatric ambulatory surgery. *Anaesth Analg*, 88: 246-250.
18. McEwen, A., Moorthy, C., Quantock, C., Rose, H., & Kavanagh, R. (2007). The effect of videotaped preoperative information on parental anxiety during anesthesia induction for elective pediatric procedures. *PediatrAnesth*, 17, 534-539.
19. William Li HC, Lopez V, Lee TL (2007) Effects of preoperative therapeutic play on outcomes of school age children undergoing day surgery. *Res nurs health*, 30(3): 320-332.

APPENDIX-1D

ST. JOHN'S MEDICAL COLLEGE & HOSPITAL
BANGALORE - 560 034, INDIA



INSTITUTIONAL ETHICAL REVIEW BOARD

Telephone : (080) 2065057
Fax : 91-80-5531786
Email : clepidsjmc@vsnl.com
joydavid@vsnl.com
karunark@yahoo.com

IERB OFFICE
Ground Floor
College Building

Ref No.:

Date:

No.8/PD/1091/2002

August 28, 2002

Ms. Preethy D'Souza
Assistant Professor
Dept. of Child Health
COLLEGE OF NURSING
S. J. N. A. H.S.

Sub: Approval of Research Proposals by the I.E.R.B.

Dear Ms. Preethy,

I wish to inform you that your Research Project entitled: "IMPACT OF PRE-OPERATIVE BEHAVIOURAL PROGRAMME ON PERIOPERATIVE OUTCOMES IN CHILDREN (5-12 YEARS) UNDERGOING EFFECTIVE SURGERY AND THEIR PARENTS IN A SELECTED MEDICAL COLLEGE HOSPITAL IN BANGALORE", has been approved after clarification of certain points raised by the Executive Committee of the Institutional Ethical Review Board, S.J.M.C.H., at its Meeting held on 27th May 2002 and the Director, SJNAHS. You can commence your work on your Research Project on the condition that you inform the I.E.R.B. of the following:

1. The Occurrence of Serious Adverse Events\Drug Reactions and/or Death, while conducting this Trial.
2. (a) Discontinuation (b) Abandonment (c) Completion of this Trial, stating the reasons, if the situation of 2(a) or 2(b) is encountered.
3. (a) It is mandatory that a 6 monthly Interim Review Report on the status of the project be submitted to the Convenor.
3. (b) On completion of the above Research Project - the Principal Investigator is responsible for submitting a brief summary of the Results obtained, to the Convenor of the Institutional Ethical Review Board - I.E.R.B., through the Chairperson/Dean.

With best wishes,

Yours sincerely,

Mary M. Ollapally
(Dr. Mary M. Ollapally, MD BA)
DEAN

cc:

Convenor I.E.R.B.
Supdt. Accts. SJMCH
Medical Supdt. SJMCH

Dean
St. John's Medical College
Bangalore - 34

Reproduced with permission of copyright owner. Further reproduction prohibited without permission.