

The effectiveness of the care program is based on the comfort theory on the level of anxiety in children candidates for endoscopy referred to the endoscopy center of Hajar Shahrekord Hospital affiliated Shahrekord university of medical sciences

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Abstract

Background: Endoscopy is an invasive diagnosis and treatment procedure that can create an anxiety in children. The use of nursing theories as a comprehensive nursing care model has a significant role in improving people's health. This study aims to examine the effects of the comfort-theory-based care model on the anxiety level of children undergoing endoscopy at the endoscopy center of Hajar Hospital in Shahrekord, Iran.

Method: This clinical trial was conducted with on 56 children referred to the endoscopy center of Hajar Hospital in Shahrekord, in 2022. Sampling was done by convenience method among eligible children, who were later divided into two intervention and control groups by random allocation method. The intervention group received a care program based on comfort theory two hours before the start of endoscopy. Data collection tools included a demographic information form and the modified Yale anxiety scale; and the statistical analysis were performed through SPSS-22 software, using independent t-test, paired t-test, chi-square test and Fisher's exact test at a significance level of $p < 0.05$.

Results: Mean score of anxiety before the intervention was 42.04 ± 11.47 in the intervention and 44.03 ± 8.86 in the control group, which showed no statistically significant difference ($p = 0.470$). But after the intervention, the mean score of anxiety increased to 24.11 ± 7.3 in the intervention group and 49.88 ± 11.98 in the control group, which showed a statistically significant difference ($p = 0.009$).

Conclusion: According to the results, using a care program based on comfort theory was effective in reducing the anxiety of children undergoing endoscopy; so, this care model is recommended to be implemented for children undergoing invasive procedures.

Key Words: Anxiety, Care program, Children, Comfort theory, Endoscopy, Relief.

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1- INTRODUCTION

Endoscopy is a reliable method for detecting organic lesions that cannot be detected by conventional examinations (1). Every year, nearly 1% of the world population needs this procedure so that in the UK alone more than 10 out of every 1000 people have done this procedure and in some areas, 15 out of every 1000 people have undergone endoscopy (2). Endoscopy is a direct observation of the digestive system with a flexible tube (3). In addition to its benefits, this method is associated with several complications, including infection, bleeding, perforation and respiratory issues, along with physiological effects of sedative drugs (4). Reduction of complications in invasive procedures requires careful measures, and people need to be mentally and emotionally prepared before performing endoscopy (5, 6). Psychological preparation is more focused on reducing anxiety, because people who undergo invasive procedures experience high anxiety levels (7). Anxiety is an indeterminate, subjective and vague feeling with an unknown origin, which causes restlessness and stress in people (8). Anxiety is also a psychological and physiological state that has cognitive, physical, emotional and behavioral components, which if combined, create an unpleasant feeling such as restlessness, apprehension, fear, concern, etc. (9). Anxiety is often caused by being in a strange situation or sensing a possibility of death or discomfort, which changes the body function (10). Anxiety and fear of invasive procedures in children are caused by lack of understanding, limited control over the environment, situation and feelings related to the procedure (11), psychological immaturity, facing new and unfamiliar situations, meeting strangers and being separated from parents (12). According to Langford's study, 6-12-year-old children have developed logical

thinking, but they have incorrect assumptions in situations such as medical and surgical procedures, which can cause anxiety and distress in them (13). Hagi Wara et al. (2015), in their study, reported that 80% of children aged 1 month to 17 years' experience anxiety before endoscopy (14).

Anxiety before endoscopy leads to decreased tolerance and cooperation, prolongation of procedure, increased use of sedatives (15), increased complications, and physician's problem to perform diagnostic and therapeutic interventions (16). Children do not have the intellectual and psychological skills necessary to deal with anxiety (17), so it is necessary to control their anxiety before performing invasive procedures such as endoscopy. In children, general anesthesia and sedatives are used to reduce mental and physical stress caused by endoscopy (18). The use of sedatives is not without harmful effects, as it has been shown that, in addition to increasing the treatment cost for patients by 30% to 50%, the use of sedatives leads to prolongation of patient relief and recovery (19). Also, in addition to imposing costs on the health system, sedative drugs can suppress the respiratory and cardiovascular systems, and patients who receive these drugs need more time to regain their full consciousness (20).

Since nurses spend more time with children in comparison to other members of the treatment team, they are in the best position to reduce children's anxiety (21), and one of the most important duties of nursing staff is to pay attention to procedures that cause anxiety and also take appropriate nursing measures to reduce anxiety (22). Nurses should use comprehensive, high-quality and modern care plans to carefully examine the condition of children undergoing invasive procedures, to provide quality care for children, and to detect and manage

complications by taking necessary nursing measures (23).

One of the best ways to achieve a comprehensive care plan is to use nursing theories in the form of a clinical nursing care model (23, 24). The use of nursing theories, as a comprehensive clinical nursing care model, has a significant role in managing diseases and improving people's health. One of these theories is the theory of comfort, which can be used to develop a comfort theory-based care model. This model is a dynamic and purposeful care model that can be used to reduce mental distress and pain in physical, psychological, spiritual, socio-cultural and environmental dimensions (25). It is very useful for children as a suitable option, because children and their families want to be comfortable in stressful clinical situations (23). Although the final goal of nursing care is to improve patient comfort (26), comfort can also be considered as an important criterion for the initial assessment, discharge and management of patient before performing procedures, such as endoscopy, that require sedations. Any problem such as anxiety before invasive procedures will have a negative effect on the comfort of the patient; and, it is important to pay attention to the comfort of the patient during invasive procedures (27). There have been limited studies on how to create peace and comfort in children. Currently there is a great deal of interest among the researchers of pediatric nursing to invent and develop new strategies to create comfort in children and their families, because comfort is considered a comprehensive and important outcome in nursing and child care. Studies have shown that comfort theory can be successfully used at clinical settings (23). Khaleghi et al. investigated the effect of comfort theory-based care models on the distress, pain and hemodynamic conditions of children after surgery for congenital heart defects. They showed that the

implementation of the nursing care model reduced pain and improved some hemodynamic indicators (28). In another study by Chandra (2013), the use of this model improved the children's comfort level (29). Accordingly, the aim of this study was to investigate the effect of comfort theory-based care models on the level of anxiety in children undergoing endoscopy.

2- MATERIALS AND METHODS

2-1. Design and population

This is a clinical trial (registered in the clinical trial center with the code (4N20190303042900 IRCT). The research population consisted of 7-12-year-old children undergoing endoscopy at the endoscopy center of Hajar Hospital in Shahrekord.

Criteria for entering the study included being interested in taking part in the study, being 7-12 years old, needing endoscopy, being literate, not having hearing, vision or communication disorders, not having known anxiety disorders and hyperactivity based on medical records, not having a history of endoscopy, and being accompanied by one of the parents. Children and their families who did not cooperate with the researcher were excluded from the study.

2-2. Sample size and sampling:

The sample size of this study was calculated to be 52 people (n=26 in each group) based on the study of Yesim Aksoy Derya et al. (2017), taking into account the first type error of 0.01, the second type error of 0.05, the difference of 7 units in the comfort score of the two groups after the intervention, and the standard deviation of 8.79 and 9.30. However, after considering 20% possibility of sample drop, 28 children were considered for each group, using the following formula (30).

$$N = \frac{(s_1^2 + s_2^2)(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2}{(\mu_1 - \mu_2)^2}$$

The participants were selected by convenience method among the patients referred to the endoscopy center of Hajar Hospital in Shahrekord. The patients, who met the inclusion criteria, were included in the study after providing a written informed consent. Then a random allocation method (red and blue balls) was used to assign the participants to two groups of intervention and control.

2-3. Data collection tool

The required data was collected using a multi-part questionnaire. The first part was related to demographic information, which included the child's age, gender, educational level and birth ranking in the family, as well as the parents' educational level and occupation. The second part included the modified version of Yale Preoperative Anxiety Scale. This tool, which was invented by Kane et al. (1997), has 22 items that assess children's preoperative anxiety in 5 areas of activity, tone of voice (speaking), expression of feelings and emotions, obvious arousal or irritation (excitement), and relying on parents. Each area of the modified Yale scale is scored with different levels of behaviors related to that area. Some of these areas have 4 or 6 items. The scoring system in this scale is based on the Likert method.

The reliability of this scale was calculated to be 0.86 by the inter-observer agreement method in the study by Kane et al. (1997), and its validity was calculated at 0.79 by the concurrent validity method (31). The reliability of this tool in the present study was calculated to be 0.85, using Cronbach's alpha method.

2-4. Implementation method

Before conducting the intervention, the modified Yale anxiety scale and the demographic information questionnaire were completed by the researcher in both groups. In the intervention group, the care model was implemented two hours before

the start of endoscopy in a quiet room within the waiting room.

The intervention was conducted in 4 dimensions (physical, psychological-spiritual, cultural-social and environmental) and three areas (relief, comfort and excellence). In this regard, the intervention in the physical dimension contained measures such as examining and recording vital signs, giving a comfortable position, providing a suitable seat, and allowing the presence of parents. The intervention in psychological-spiritual dimension included active listening to the child, allowing parents to stay with the child, psychological-emotional support of the child, having positive conversation with the child, preparing the child according to his/her developmental age, and allowing the child to watch cartoon before starting the procedure (the cartoons were downloaded based on the children's interest and were displayed on smartphone). The intervention in cultural-social dimension consisted of providing a sense of trust, respecting cultural and local traditions (reading the Quran and prayer), using body language in an appropriate way and giving appropriate information according to the developmental age of the child, supporting the child and his/her family, asking the parents to stay with the child until the time of procedure to divert the child's thought, and allowing the child to watch cartoon before the procedure. The intervention in the environmental dimension included establishing silence, order and security, as well as controlling the light and ambient noise as much as possible (endoscopy of children was performed at a specific time when only the children were present, while movement of all personnel and nursing students was limited).

The intervention group received educational materials, while the control group only received the center's routine training. Half an hour after the

intervention, the post-test was carried out and the questionnaire was completed again by the researcher in the intervention and control groups. After the intervention, physiological indicators were also measured by the researcher and the obtained results were compared with the previous results.

2-5. Data analysis

The obtained data was analyzed by SPSS software version 22. To describe the data, frequency and percentage indices were used for qualitative variables and mean \pm standard deviation indices were applied for quantitative variables with normal distribution. To check the difference between the two groups, Fisher's exact test and chi-square test were used for qualitative variables, and independent t-test and paired t-test were used for

quantitative variables with normal distribution. The significance level of 0.05 was considered for all tests.

3- RESULTS

The mean age of the participants in the intervention group was 9.29 years with the standard deviation of 1.52, and in the control group, it was 9.61 years with the standard deviation of 1.54. Before the intervention, the independent t-test showed no significant difference between the two groups in terms of the mean age ($p=0.435$). Also, the obtained results showed that in terms of gender ($p=0.781$), level of education ($p=0.993$), birth ranking in the family ($p=0.585$), father's occupation ($p=0.932$), mother's occupation ($p=0.335$), father's education ($p=0.918$), mother's education ($p=0.918$), the two groups were homogenous (**Table 1**).

Table-1: Demographic characteristics of the participants in the two groups

Variable		Intervention group		Control group		Significance
Gender	Boy	19	67.9	17	60.7	*0.781
	Girl	9	32.1	11	39.3	
	Total	28	100	28	100	
Level of education	Grade1 (primary school)	10	35.7	10	35.7	**0.993
	Grade 2	6	21.4	6	21.4	
	Grade 3	5	17.9	5	17.9	
	Grade 4	4	14.3	3	14.3	-
	Grade 5	2	7.1	2	7.1	
	Grade 6	1	3.6	2	7.1	
Total	28	100	28	100		
Birth ranking in the family	First	10	35.7	13	46.4	**0.585
	Second	10	37.5	11	39.3	
	Third	5	17.8	3	10.7	
	Fourth and above	3	10.7	1	3.5	
	Total	28	100	28	100	
Father's occupation	Office worker	6	21.4	5	17.9	**0.932
	Teacher	3	10.7	5	17.9	
	Tutor	1	3.6	1	3.6	
	Self-employed	12	42.9	10	35.7	
	Laborer	6	21.4	7	25	
	Total	28	100	28	100	
Mother's occupation	Office worker	2	7.1	7	25	0.335
	Teacher	3	10.7	4	14.3	
	Tutor	1	3.6	0	0	
	Self-employed	4	14.3	3	10.7	

	Housekeeper	18	64.3	14	50	
	Total	28	100	28	100	
Father's education	Secondary school	2	7.1	9	32.1	**0.918
	High school diploma	13	46.4	7	25	
	bachelor's degree	11	39.3	11	39.3	
	Master's degree and higher	2	7.1	1	3.6	
	Total	28	100	28	100	
Mother's education	Secondary school	10	35.7	9	32.1	**0.918
	High school diploma	8	28.6	9	32.1	
	bachelor's degree	9	32.1	8	28.6	
	Master's degree and higher	1	3.6	2	7.1	
	Total	28	100	28	100	

*Independent t-test

**Fisher's exact test

*** Chi-square test

The difference in anxiety scores in the intervention and control groups is shown in **Tables 2** and **3**, respectively. **Tables 2** to **4** indicate the percentage of children in 5 areas of activity (4 levels), speaking (6 levels), expressing emotion (4 levels), excitement (4 levels), and relying on parents (4 levels) before and after the intervention. According to **Table 2**, after

the intervention, the activity, speaking, expressing emotions, excitement and relying on parents in the intervention group were at a more favorable level compared to pre-intervention levels; so that a statistically significant difference could be observed in the scores of above indexes in the intervention group before and after the intervention ($P > 0.05$).

Table-2: The mean scores of anxiety in the intervention group before and after the intervention

Dimension	Frequency (%)				Pre-test				Post-test				Paired t-test	Significant level
	1	2	3	4	5	6	1	2	3	4	5	6		
Activity	3.6	7.2	21.6	68.4	-	-	7.2	21.6	3.6	3.6	-	-	-	0.001
Speaking	0	3.6	3.6	14.4	39.6	39.6	68.4	14.4	7.2	7.2	3.6	0	-	0.000
Expressing emotion	3.6	10.8	25.2	61.2	-	-	57.6	18	10.8	14.4	-	-	-	0.009
Excitement	3.6	21.6	28.8	46.8	-	-	68.4	18	10.8	3.6	-	-	-	0.000
Relying on parents	3.6	10.8	32.4	54	-	-	61.2	25.2	10.8	3.6	-	-	-	0.000

According to **Table 3**, a significant difference could also be observed in the mean scores of activity, speaking, expressing emotions, excitement and relying on parents in the control group before and after the intervention ($p < 0.05$).

3-1. Activity index

Before the intervention, 10.8% of children in the intervention group and 14.4% in the control group were at level 1 and 2 of the

activity index, while 90% of children in the intervention group and 86.4% in the control group were at levels 3 and 4 of the activity index. After the intervention, however, 86.4% of children in the intervention group and 7.2% in the control group were at levels 1 and 2 of activity index, while 3.6% of children in the intervention group and 89.3% in the control group were at level 3 and 4 of activity index.

Table-3: The mean scores of anxiety in the control group before and after the intervention

Dimension	Frequency (%)				Pre-test				Post-test				Paired t-test	Significant level
	1	2	3	4	5	6	1	2	3	4	5	6		
Activity	3.6	10.8	36	50.4	-	-	0	3.6	43.2	54	-	-	-	0.000
Speaking	0	3.6	7.2	25.2	28.8	36	0	0	3.6	25.2	32.4	39.60	-	0.015
Expressing emotion	10.8	14.4	25.2	50.4	-	-	3.6	21.6	32.4	43.2	-	-	-	0.013
Excitement	7.2	3.6	32.4	57.6	-	-	3.6	10.8	25.2	61.2	-	-	-	0.001
Relying on parents	3.6	14.4	36	46.8	-	-	0	10.8	39.6	50.4	-	-	-	0.003

3-2. Speaking index

Before the intervention, 7.2% of children in the intervention group and 10.8% in the control group were at levels 1, 2 and 3 of the speaking index, while 93.6% of children in the intervention group and 90% in the control group were at levels 4, 5 and 6 of the speaking index. After the intervention, however, 90% of children in the intervention group and 3.6% in the control group were at levels 1, 2 and 3 of the speaking index, while 10.8% of children in the intervention group and 97.2% in the control group were at levels 4, 5 and 6 of the speaking index.

3-3. Expressing emotion index

Before the intervention, 14.4% of children in the intervention group and 25.2% in the control group were at levels 1 and 2 of this index, and 86.4% of children in the intervention group and 75.9% in the control group were at levels 3 and 4 of expressing emotion index. After the intervention, 75.6% of children in the intervention group and 25.2% in the control group were at level 1 and 2 of this index, and 25.2% of children in the intervention group and 75.6% in the control group were at levels 3 and 4 expressing emotion index.

3-4. Excitement index

Before the intervention, 25.2% of children in the intervention group and 10.8% in the

control group were at levels 1 and 2 of the excitement index, and 75.6% of children in the intervention group and 90% in the control group were at levels 3 and 4 of the excitement index. After the intervention, 86.4% of children in the intervention group and 14.4% in the control group were at levels 1 and 2 of the excitement index, and 14.4% of children in the intervention group and 86.4% in the control group were at levels 3 and 4 excitement index.

3-5. Index of relying on parents

Before the intervention, 14.4% of children in the intervention group and 18% in the control group were at levels 1 and 2 of this index, and 86.4% of children in the intervention group and 82.8% in the control group were at levels 3 and 4 of above index. After the intervention, 86.4% of children in the intervention group and 10.8% in the control group were at levels 1 and 2 of this index, and 14.4% of children in the intervention group and 90% in the control group were at levels 3 and 4 of this index.

Comparing the level of anxiety between the two groups showed no significant difference in all anxiety indices before the intervention ($p > 0.05$). But after the intervention, all anxiety indices significantly improved in the intervention group compared to the control group ($p = 0.000$).

Table-4: The mean scores of anxiety in the intervention and control groups after the intervention

Dimension	Frequency (%)				Pre-test				Post-test				Paired t-test	Significant level
	1	2	3	4	5	6	1	2	3	4	5	6		
Activity	72	21.6	3.6	3.6	-	-	3.6	3.6	43.2	50.4	-	-	-	0.000
Speaking	68.4	14.4	7.2	7.2	3.6	-	-	-	-	25.2	32.4	39.6	-	0.000
Expressing emotion	57.6	18	10.8	14.4	-	-	3.6	21.6	32.4	43.2	-	-	-	0.000
Excitement	68.4	18	10.8	3.6	-	-	3.6	10.8	25.2	61.2	-	-	-	0.000
Relying on parents	61.2	25.2	10.8	3.6	-	-	0	10.8	39.2	50.4	-	-	-	0.000

4- DISCUSSION

This study was conducted to investigate the effect of comfort theory-based care models on the level of anxiety of children undergoing endoscopy. The comparison of mean anxiety score before and after the intervention between the intervention and control groups showed that the comfort theory-based care model had a positive effect on the anxiety of children undergoing endoscopy. In this regard we can say that the care model was able to improve the children's behavior, thought and coping skills in stressful situations, and also remove obstacles such as negative feelings, making them feel relaxed after a while. In line with this result, Kolcaba et al. (2004), using the comfort care model among patients before anesthesia showed that this model reduced anxiety in samples. This nursing care model is a targeted and dynamic model for patients and families in all health care organizations. It also reduces the physical, mental-psychological, and cultural-social complications of patients and increases their satisfaction from the health care team (32). It can be said that this care model creates a kind of cognitive control that reduces the destructive effect of anxiety and increases the health knowledge of patients. Kolcaba says that nursing interventions based on comfort theory can be used as a guide to meet people's needs in regard to comfort (33).

Khaleghi et al. (2017) in their study conducted on the effect of care model based on comfort theory on distress, pain and hemodynamic conditions of children after surgery for congenital heart defects showed that, this model was able to reduce distress and pain and also improve some hemodynamic indicators of patients (28). Therefore, it is necessary to pay attention to the needs of children during hospitalization for effective child care. Kolcaba et al. (2005), investigated the effects of comfort theory in a case study of pediatric nursing on 12-year-old girls with scoliosis undergoing surgery. The results revealed that the comfort theory had positive effects on empowering children and their families and caused health-seeking behaviors in them. Increasing health in children and families at the clinical setting is a friendly, practical and positive outcome measure (34). Therefore, the comprehensive view of this theory on all care needs of children becomes an effective factor in increasing the quality of pediatric care. Anika et al. (2016), in a qualitative study, showed that the use of comfort theory in the preoperative stage helped the nurse anesthetists to identify the patient's individual needs, so it is valuable to adapt and initiate comfort measures and interventions. Thus, nurses can use this model to identify a patient's needs and increase their comfort before performing invasive procedures (35). Liu et al. (2015) also demonstrated that this approach led

the mean score of pain, fatigue, relief and other complications in the intervention group to become lower than that of the control group. The implementation of comfort theory was able to reduce the pain and complications as well as heart attack and mortality in patients (36). Education has been able to help patients adapt effectively to changes in health status. It also increases patient satisfaction, improves quality of life, ensures continuity of care, relieves pain, and reduces the likelihood of complications. Yasimi et al. (2017) showed that nursing care based on comfort theory for women undergoing cesarean surgery helps midwives to meet their comfort needs and increase their level of comfort after childbirth (37), which is in line with the results of present study. It seems that this training has been able to change the mental state of women and make them free from stressful thoughts. It should be noted that in the related literature, no study could be found to contradict the findings of the present study. Therefore, the results of the present study, overall, demonstrate that the use of a care model based on comfort theory increases the comfort and acceptance of children and decreases the level of anxiety in patients.

5- CONCLUSION

The results of the present study indicated the effective role of the comfort-theory-based care model in reducing the anxiety of children before having invasive procedures such as endoscopy. So, we recommend that nurses should check the child's comfort needs, including physical, psychological-spiritual, cultural-social and environmental needs, before performing any invasive procedure, and use this care model to resolve any discomfort. Furthermore, the results obtained from this study indicate that the use of non-pharmacological methods (care models) can play an effective role in reducing anxiety before invasive procedures in

children aged 7 to 12 years. Therefore, conditions should be provided to implement these methods in order to reduce children's anxiety in clinical environments, so that these children can effectively overcome their anxiety.

6- ETHICAL CONSIDERATIONS

The method and objectives of the study were explained to the participants and they were informed that they can withdraw from the study whenever they wished. They were also assured that their personal information would remain confidential, and written informed consent was obtained from them. The Ethics Committee of Shahrekord University of Medical Sciences approved this study with the ethics code: ID 125. 1400IR.SKUMS.REC.

7- CONFLICT OF INTEREST

None.

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