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The Effect of Inhaler Treatment with a Therapeutic Nebulizer Designed with 3D Printing Technology on Children's Psychosocial Symptoms

3D Baskı Teknolojisi ile Tasarlanan Terapötik Nebülizatör Cihazı ile Yapılan İnhaler Tedavinin Çocukların Psikososyal Semptomlarına Etkisi

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Abstract

Objective: This research was carried to minimize psychosocial symptoms such as fear, anxiety and crying by hospitalized children undergoing inhaler treatment with a nebulizer developed with three-dimensional printing technology and to examine the effect of this method on parental satisfaction.

Methods: The study is of experimental design. 44 children between the ages of 2-7 receiving inhaler therapy with a nebulizer and their parents were recruited into the experimental and control groups. The researchers collected the data with "Scale for Identifying Psychosocial Symptoms in Hospitalized Children" and the "PedsQL Healthcare Satisfaction Scale."

Results: It was noted that 45 of the children included in the study were boys, 43 were between the ages of 2-3, 75 were receiving treatment for bronchitis, 50 had previously been hospitalized for the same sickness and 68 had previously received inhaler therapy. It was observed that among the parents, 83 were mothers, 39 had a primary school education or less, and 76 were unemployed. In the experimental group, 81.8 percent of the children being treated with a 3D therapeutic device who had previously received treatment in the same way were not fearful, while 27.3 percent of those being treated with a standard type of nebulizer in the control group were unafraid ($X^2 = 24.246$; $p < 0.001$). While those who were not crying at the time of their therapy made up 71.9% in the experimental group, this rate was 36.4 percent in the control group ($X^2 = 28.686$; $p < 0.001$). The difference between the groups was significant ($p < 0.001$). The t-test performed to compare the pre- and posttests in the experimental group revealed a significant difference of $p = 0.002$. In the control group, where $p = 0.051$, no significant difference was seen. In the comparisons of the Healthcare Satisfaction Scale (PedsQL), the difference between the mean scores of the experimental and control groups was found to be significant ($p = 0.026$).

Conclusions: It was concluded that inhaler therapy administered with a therapeutic nebulizer designed with three-dimensional printing technology reduced psychosocial symptoms and positively impacted parental satisfaction. This study highlights that was carried out with the aim of minimizing psychosocial symptoms by hospitalized children undergoing inhaler treatment with a nebulizer developed with three-dimensional printing technology.

Keywords: Child, Inhalers, Hospitalization, Psychosocial Symptom, Three-Dimensional Printing, Therapeutics.

Özet

Amaç: Bu çalışma; 3D baskı teknolojisi ile geliştirilen nebülizatör cihazı ile yapılan inhaler tedavinin hastanede yatan çocuklarda tedaviye ilişkin korku, anksiyete, ağlama gibi psikososyal semptomları en aza indirmek ve ebeveyn memnuniyetine etkisini incelemek amacıyla gerçekleştirildi.

Yöntem: Araştırma deneysel tasarımdır. Deney ve kontrol gruplarına yaşları 2-7 arasında nebülizatörle inhaler tedavisi gören 44 çocuk ve ebeveynleri alındı. Veriler araştırmacı tarafından hazırlanmış 'Kişisel Bilgi Formu' ile 'Hastanede Yatan Çocuklar İçin Psikososyal Semptomları Tanılama Ölçeği' ve 'Pedsql Sağlık Bakımı Memnuniyet Ölçeği' ile toplandı.

Bulgular: Çalışmaya dahil edilen çocukların 45'inin erkek, 43'ünün 2-3 yaş, 75'inin bronşit tedavisi aldığı, 50'sinin daha önce aynı hastalık nedeniyle hastaneye yattığı ve 68'inin daha önceden inhaler tedavi aldığı görüldü. Ebeveynlerin 83'ünün anne, 39'unun eğitim durumunun ilköğretim ve altı eğitim seviyesinde, 76'sının çalışmadığı görüldü. Deney grubunda 3D terapötik cihazla önceden tedavi alanlarda tedavi esnasında korkmayanların yüzdesi 81,8 iken kontrol grubunda standart tip nebülizatör ile tedavi alanlarda 27,3 ($X^2 =$

24,246; $p < 0,001$); deney grubunda şu an ağlamayanların yüzdesi 71,9 iken kontrol grubunda 36,4 ($X^2 = 28,686$; $p < 0,001$) olup gruplar arasındaki farklılık anlamlı görüldü ($p < 0,001$). Deney grubu ön test-son test karşılaştırmalarında yapılan t testi sonucu $p = 0,002$ olup anlamlı farklılık saptandı. Kontrol grubunda ise $p = 0,051$ olup anlamlı farklılık saptanmadı. Sağlık Bakım Memnuniyet Ölçeği (PedsQL) karşılaştırmalarında deney ve kontrol grubu puan ortalamaları arasındaki fark anlamlı bulundu ($p = 0,026$).

Sonuç: 3D teknolojisi ile tasarlanan terapötik nebulizatör cihazı ile yapılan inhaler tedavinin psikososyal semptomları azalttığı ve ebeveyn memnuniyetine etki ettiği sonucuna varıldı. 3D teknolojisi ile tasarlanan nebulizatör cihazı ile yapılan inhaler tedavisi çocuklarda psikososyal semptomları azaltmak için hem klinikte hem de acil servislerde uygulanabilir.

Anahtar Kelimeler: Çocuk, İnhaler, Hastaneye Yatış, Psikososyal Semptom, 3D Baskı Teknolojisi, Tedavi.

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INTRODUCTION

Aerosol therapy is the typical treatment modality for respiratory infections in children. Its main purpose is to humidify the respiratory tract, dilute sputum and discharge it smoothly, and achieve treatment of the disease (1-3). Pediatric health management is a strictly professional challenge. Establishing good interaction with children is a priority problem and a difficult task for nurses helping children receive such treatment during hospitalization (4,5).

The nebulizer devices frequently used in pediatric treatment operate at high pitch and are generally of the appearance and type that actually diminish a child's treatment compliance. Most children exhibit signs of fear, are resistant and even unwilling to use the inhaler, believing that the disease cannot be treated, all of which leads to incredible frustration for both family and nurses (2,6). A prolonged hospital stay not only affects the timeliness of treatment, but also impacts the disease recovery process (4). Any crisis that a child may experience concerning an illness or as a result of the hospital stay may cause developmental trauma and leave a lasting scar (7,8). Nurses need to engage in nursing initiatives that will serve to eliminate psychosocial issues and increase the capacity of the hospitalized child and the family to adapt (2,6,7).

The nebulizer devices frequently used in pediatric treatment operate at high pitch and are generally of the appearance and type that actually diminish a child's treatment compliance (9,10). The issue of a child's anxiety over the device's arrival is commonly encountered. Some studies have pointed to a lessening of treatment efficacy due the fear and anxiety children experience in response to the appearance, emitted sounds and noises of hospital nebulizers and cold steam humidifiers (4,6). Nurses should use therapeutic approaches in their effort to

increase a child's compliance, clearly identifying and eliminating the negative impact that medical devices may have on children (2,6).

The aim of this study was to reduce the psychosocial symptoms of children receiving inhaler therapy with a nebulizer developed by the researchers with 3D printing technology (3D-TND-3D Therapeutic Nebulizing Device) and at the same time, to increase parental satisfaction. Three-dimensional (3D) printing technology is a rapidly developing technique that has been used in various fields today. 3D printing is a printing process which enables a hard copy printout to be obtained from any three-dimensional model. The capability of this technique to reduce both production costs and the need for raw materials and produce an end-product from only the amount of raw materials that is needed for the project differentiates this technology from traditional processes (2,3). The need for visual materials has also grown in nursing care services, and consequently, the use of visual aids has become more widespread (11,12).

Integrating updated technology such as 3D printing into the sphere of healthcare has made a higher quality of healthcare services available to patients and their caregivers (2). As a result, nurses who aim to provide their patients with holistic care can now more minimize any psychosocial symptoms or complications they may observe.

Aim

This research was carried out to of minimise psychosocial symptoms such as fear, anxiety and crying behavior displayed by pediatric in patients undergoing inhaler treatment with a nebulizer developed with 3D printing technology (3D-TND), and to examine the effect of this method on parental satisfaction.

METHODS

Participants were asked to sign a Participant Informed Consent Form in the conduct of the study. The researcher explained to the 88 parents taken into the 3D-TND and SND (Standard Nebulizer Device) groups about the purpose of the study and what was expected of them, pointing out that participation was based on volunteerism and that they could withdraw from the study at any time they wished to do so. Permission for the conduct of the study was obtained from the Clinical Studies Ethics Committee of a university date and no: (2018-172-01/08) and from the administration of the hospital in which the research was being carried out.

3D-TND: It is a device that looks like a turtle nebulizer device designed and produced by researchers using a 3D printer to be used in device research. Before the device was produced,

researcher N.A received training on three-dimensional printers and designed the device. In the printing, attention was paid to the use of raw materials that would harm children's health and a therapeutic appearance that would not cause fear and anxiety in the people in the appearance. It is a prototype device produced for device research. Division of the device regarding technical information when necessary. Please see Fig. 1.

1.1.Place and time of the study

The research was conducted as an experimental, analytical study. The study was carried out in one of the two hospitals in the city of Turkey with a pediatric clinic. The researchers determined which hospital the study would be conducted in by means of a lottery draw. The institution where the study was carried out had a specialized pediatric clinic with a 30-bed capacity. The study took place over the period November 15, 2018 - May 15, 2019.

1.2.Participants

It was noted that 403 pediatric inpatients receiving inhaler treatment who had been hospitalized for upper respiratory tract conditions in this clinic over the past 6-month period. Among these children, 246 between the ages of 2-7 constituted the universe of the study. A sample size calculation for a known population made from this universe at a 95% confidence interval and 5% significance determined that the sample size would be 120. Ninety-six children of those in the sample agreeing to be included in the research at the time the study was being conducted were included. Power analysis was used for sample calculation. In case the effect width value was 0.70 at a 5% margin of error and 81.23% power level, the total number of individuals was determined as 88, including 44 patients for two repeated measurements in the groups (13). The random number table was used to determine the 3D-TND and SND groups in the study. The children hospitalized in the clinic with the mentioned diagnoses were assigned to the 3D-TND and SND groups in the order of their date of admittance as from the start of the study. For example, while one pediatric patient was 5th to be admitted for treatment and assigned to the 3D-TND group, the child 11th to be admitted was assigned to the SND group. This method was chosen to avoid bias. The study was completed with 88 pediatric patients are distributed to semi-half groups.

1.3.Instruments

Personal information form

This form consists of information on each child, namely the variables of gender, age, medical diagnosis, duration of hospitalization, previous hospitalizations, how many times the child has

been hospitalized, if ever, whether or not the child had previously received steam/nebulizer therapy.

Scale for Identifying Psychosocial Symptoms in Hospitalized Children (SIPS)

Üstün & Kelleci (2012) produced the validity and reliability study of this scale for the purpose of creating an instrument that would provide the means to identify the psychosocial symptoms of pediatric inpatients. The scale is a Likert-type of instrument with 24 items. Higher scores on the scale indicate that the hospitalized child has psychosocial issues (14). In this study, Cronbach's alpha value was calculated to be $\alpha=0.947$.

The PedsQL Healthcare Satisfaction Scale

The scale was developed by Varni (Varni, 2005) in 1999 (15). The Turkish translation, validity and reliability testing of the scale were performed by Ulus (16). A total score indicates the level at which satisfaction has been achieved. In this study, Cronbach's alpha value was calculated to be $\alpha=0.806$.

Intervention

- The data collection forms were filled out with either one of the parents of the hospitalized children in a face-to-face interview.
- The Personal Information Form comprising the descriptive characteristics of the children and their parents was used in the data collection.
- The SIPS in Hospitalized Children was used to identify the psychosocial symptoms of the hospitalized children.
- The PedsQL Scale was used to measure the parents' satisfaction with the medical services provided as well as their psychosocial satisfaction
- The inhaler therapy using the 3D-TND developed with 3D printing technology was applied from the first stage of the child's admittance into the hospital until discharge.
- The researcher responsible for data collection conducted the collection of data and the interviews with the parents.

1.4. Statistical analysis

The IBM SPSS 22.0 program was used for the statistical analysis. Descriptive statistical methods were used in the analysis of the study data. Normality was investigated with Normality Tests with Plots. The nonparametric test Mann Whitney U test and the Wilcoxon paired sample test were then employed.

RESULTS

The study results were examined in three contexts—sociodemographic findings, findings related to psychosocial symptoms and by making scale comparisons.

Findings concerning sociodemographic characteristics

Of the children in the 3D-TND group included in the study, 26 were boys and 26 were preschool children. It was observed that 42 of the parents in the 3D-TND group were mothers, 21 were under the age of 30, 36 were unemployed, 15 were in primary school, 16 were secondary school educated, 35 had an income equal to their expenses, and 21 lived in the city center. Of the children in the SND group included in the study, 25 were girls and 30 were preschool children. It was observed that 41 of the parents in the SND group were mothers, 23 were under the age of 30, 40 were unemployed, 14 were primary school, 13 were secondary school educated, 31 had an income equal to their expenses, and 22 lived in the city center.

Findings concerning psychosocial symptoms

Of the children in the 3D-TND study group, 59.1% had been previously hospitalized, 86.4% had once received inpatient nebulizer therapy. Among the children once receiving nebulizer therapy, 68.2% cried, 59.1% were fearful, 59.1% tried to avoid the treatment. In the 3D-TND group, it was found that 81.8% of the children receiving 3D-TND nebulizer treatment were not fearful and 93.2% did not exhibit crying symptoms.

Of the children in the SND group, 54.5% had been previously hospitalized, 68.2% had received inpatient nebulizer therapy in their previous hospitalization. Among the children previously receiving nebulizer treatment, 52.3% cried, 52.3% were fearful, 4.9% tried to avoid the treatment. Among their parents, 43.2% thought that they had not received effective nebulizer treatment. In the SND group, it was found that 27.3% of the children receiving SND nebulizer therapy were not fearful and 36.4% did not exhibit crying symptoms. The distribution of diagnostic and psychosocial symptom findings among the children in the 3D-TND and SND groups can be seen in Table 1.

Table 1. Distribution of diagnostic and psychosocial symptom findings among the children

Symptoms by admittance status		3D-TND (n = 44)		SND (n = 44)	
		Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)
Diagnosis	Bronchitis	41	93,2	34	77,3
	Asthma	2	4,5	7	15,9
	Pneumonia	1	2,3	3	6,8
Hospitalized previously?	Yes	26	59,1	24	54,5
	No	18	4,9	20	45,5
Previously received nebulizer treatment?	Yes	38	86,4	30	68,2
	No	6	13,6	14	31,8
Cried in previous hospitalization?	Yes	30	68,2	23	52,3
	No	9	2,5	8	18,2
	Not received treatment	5	11,4	13	29,5
Was fearful in previous hospitalization?	Yes	26	59,1	23	52,3
	No	13	29,5	8	18,2
	Not received treatment	5	11,4	13	29,5
Previously avoided treatment?	Yes	26	59,1	18	4,9
	No	13	29,5	12	27,3
	Not received treatment	5	11,4	14	31,8
Believing previous treatment was effective	Yes	14	31,8	11	25,0
	No	26	59,1	19	43,2
	Not received treatment	4	9,1	14	31,8
Feeling fearful right now	Yes	8	18,2	32	72,7
	No	36	81,8	12	27,3
Crying right now	Yes	3	6,8	28	63,6
	No	41	93,2	16	36,4
Total		44	100	44	100

The chi-square test was used in the comparison of the psychosocial symptoms of the children in the 3D-TND and SND groups. In the 3D-TND group, 76.9% of the children who had been fearful while being treated with SND were not afraid in their 3D-TND treatment and 92.3% did not cry ($p>0.05$). Of the children who had called during their SND treatment, 8.0% were not fearful during their therapy with 3D-TND and 93.3% did not cry ($p>0.05$) (Table 2.a).

Table 2.a. Comparison of psychosocial symptoms among children in the 3D-TND group who had previously received SND and were now receiving 3D-TND nebulizer treatment

			Fearful now with 3D-TND			Crying now with 3D-TND				
			Yes	No	Total	Yes	No	Total		
Fearful with SND (before)	Yes	Frequency	6	20	26	Yes	Frequency	2	24	26
		% among those fearful before	23,1	76,9	100		% among those fearful before	7,7	92,3	10,0
		% among those fearful now	75,0	55,6	59,1		% among those crying now	66,7	58,5	59,1
	No	Frequency	1	12	13	No	Frequency	0	13	13
		% among those fearful before	7,7	92,3	100		% among those fearful before	0	100	100
		% among those fearful now	12,5	33,3	29,5		% among those crying now	0	31,7	29,5
	Not received treatment	Frequency	1	4	5	Not received treatment	Frequency	1	4	5
		% among those fearful before	2,0	8,0	100		% among those fearful before	2,0	8,0	10,0
		% among those fearful now	12,5	11,1	11,4		% among those fearful now	33,3	9,8	11,4
Chi-Square = 1,430 and p = ,527						Chi-Square = 2,384 and p = ,204				
			Fearful now with 3D-TND			Crying now with 3D-TND				
			Yes	No	Total	Yes	No	Total		
Crying with SND (before)	Yes	Frequency	2	24	30	Yes	Frequency	2	28	30
		% among those crying before	2,0	8,0	100		% among those crying before	6,7	93,3	10,0
		% among those fearful now	75,0	66,7	68,2		% among those crying now	66,7	68,3	68,2
	No	Frequency	1	8	9	No	Frequency	0	9	9
		% among those crying before	11,1	88,9	10,0		% among those crying before	0	100	100
		% among those fearful now	12,5	22,2	2,5		% among those crying now	0	22	2,5
	Not received treatment	Frequency	1	4	5	Not received treatment	Frequency	1	4	5
		% among those crying before	2,0	8,0	10,0		% among those crying before	20	80	100
		% among those fearful now	12,5	11,1	11,4		% among those fearful now	33,3	9,8	11,4
Chi-Square = ,496 and p = ,855						Chi-Square = 2,026 and p = ,398				

In the SND group, 82.6% of the children who had been once fearful during their therapy with SND were fearful during their present therapy with SND and it was seen that 73.9% cried ($p < 0.05$). Among the children who had previously called in their therapy with SND, 82.6% were fearful during their present therapy with SND and it was seen that 73.9% called ($p < 0.05$) (Table 2.b).

Table 2.b Comparison of psychosocial symptoms among children in the SND group who had previously received SND and were now again receiving SND nebulizer therapy

		Fearful of SND treatment now					Crying in SND treatment now			
		Yes	No	Total			Yes	No	Total	
Fearful with SND (before)	Yes	Frequency	19	4	23	Yes	Frequency	17	6	23
		% among those fearful before	82,6	17,4	100		% among those fearful before	73,9	26,1	100
		% among those fearful before	59,4	33,3	52,3		% among those crying now	6,7	37,5	52,3
	No	Frequency	3	5	8	No	Frequency	1	7	8
		% among those fearful before	37,5	62,5	100		% among those fearful before	12,5	87,5	100
		% among those fearful before	9,4	41,7	18,2		% among those crying now	3,6	43,8	18,2
	Not received	Frequency	10	3	13	Not received	Frequency	10	3	13
		% among those fearful before	76,9	23,1	100		% among those fearful before	76,9	23,1	100
		% among those fearful now	31,3	25,0	29,5		% among those fearful now	35,7	18,8	29,5
Chi-Square = 5,568 and p = ,052					Chi-Square = 1,251 and p = ,005					
		Fearful of SND treatment now					Crying in SND treatment now			
		Yes	No	Total			Yes	No	Total	
Crying with SND (before)	Yes	Frequency	19	4	23	Yes	Frequency	17	6	23
		% among those crying before	82,6	17,4	100		% among those crying before	73,9	26,1	100
		% among those fearful now	59,4	33,3	52,3		% among those crying now	6,7	37,5	52,3
	No	Frequency	3	5	8	No	Frequency	1	7	8
		% among those crying before	37,5	62,5	100		% among those crying before	12,5	87,5	100
		% among those fearful now	9,4	41,7	18,2		% among those crying now	3,6	43,8	18,2
	Not received	Frequency	10	3	13	Not received	Frequency	10	3	13
		% among those crying before	76,9	23,1	100		% among those crying before	76,9	23,1	100
		% among those fearful before	31,3	25,0	29,5		% among those fearful now	35,7	18,8	29,5
Chi-Square = ,496 and p = ,855					Chi-Square = 2,026 and p = ,398					

Results of scale comparisons

The results of the comparisons of the pretest-posttest values of the scales in the 3D-TND and SND groups using the Wilcoxon test are given in Table 3. Accordingly, the participants in the 3D-TND group displayed a significant difference between the results of the *SIPS pre- and posttests* ($p=0.004$). This indicated that psychosocial symptoms had diminished. The

participants in the SND group displayed no significant difference between the results of the SIPS pre- and posttests ($p=0.657$).

Table 3. Comparison of pretest-posttest scale results in the 3D-TND and SND groups

		3D-TND group			SND group		
Scales		Mean \pm SD	Min	Max	Mean \pm SD	Min	Max
PedsQ Healthcare Satisfaction Scale	Receiving information (pretest)	72,22 \pm 23,40	15,00	100	69,86 \pm 18,69	2,00	100
	Receiving Information (posttest)	82,74 \pm 17,51	25,00	100	69,66 \pm 17,76	3,00	100
		$Z = -3,77$ and $p = ,001^{**}$			$Z = -,358$ and $p = ,72$		
	Family Involvement (pretest)	85,94 \pm 14,71	37,50	100	74,57 \pm 18,25	25,00	100
	Family Involvement (posttest)	89,87 \pm 16,98	25,00	100	72,77 \pm 16,76	43,75	100
		$Z = -2,347$ and $p = ,019^{***}$			$Z = -1,462$ and $p = ,144$		
	Communication (pretest)	77,77 \pm 2,97	35,00	100	66,38 \pm 19,34	25,00	100
	Communication (posttest)	85,89 \pm 17,96	25,00	100	64,05 \pm 2,64	5,00	100
		$Z = -3,527$ and $p = ,001^{**}$			$Z = -1,555$ and $p = ,12$		
	Technical skills (pretest)	83,52 \pm 17,76	37,50	100	71,59 \pm 19,01	,00	100
	Technical Skills (posttest)	85,84 \pm 21,83	,00	100	67,94 \pm 19,54	,00	100
		$Z = -1,404$ and $p = ,16$			$Z = -2,574$ and $p = ,01^{***}$		
	Emotional Needs (pretest)	71,23 \pm 24,62	25,00	100	56,59 \pm 25,73	,00	100
	Emotional Needs (posttest)	78,03 \pm 25,53	,00	100	54,40 \pm 27,04	,00	100
		$Z = -1,62$ and $p = ,105$			$Z = -1,3$ and $p = ,194$		
	General Satisfaction (pretest)	89,58 \pm 13,82	41,67	100	73,86 \pm 17,29	41,67	100
	General Satisfaction (posttest)	92,80 \pm 13,76	25,00	100	7,83 \pm 18,28	41,67	100
SIPS		$Z = -1,228$ and $p = ,22$			$Z = -1,78$ and $p = ,075$		
	PedsQL Total (pretest)	477,02 \pm 98,13	221,67	600	411,58 \pm 98,53	22,00	600
	PedsQL Total (posttest)	511,62 \pm 95,25	15,00	600	399,67 \pm 101,87	228,33	600
		$Z = -2,798$ and $p = ,005^{***}$			$Z = -1,855$ and $p = ,064$		
	SIPS Total (pretest)	27,34 \pm 13,08	1	48	24,34 \pm 1,27	7	48
	SIPS Total (posttest)	22,48 \pm 13,64	,00	48	25,09 \pm 1,23	5,00	48
		$Z = -2,867$ and $p = ,004^{***}$			$Z = -,444$ and $p = ,657$		

* Wilcoxon test, ** $p < .001$, *** $p < .05$

It was seen in the examination of the PedsQL Healthcare Satisfaction Scale that there was a significant difference between the participants in the 3D-TND group ($p=0.005$). In the pretest-posttest comparison of the PedsQL of the participants in the SND group, there wasn't significant difference ($p=0.064$). In the results of the pretest-posttest comparisons of the subscales of the PedsQL, it was seen that the 3D-TND group had significant differences in the receiving information ($p=0.001$), family involvement ($p=0.019$), and communication ($p=0.001$) subscales while only the technical skills subscale displayed a significant difference ($p=0.01$) in the SND group. The results of the comparisons of the pretest-posttest values of the scales in the 3D-TND and SND groups in Table 4. Accordingly, there wasn't significant difference between the *SIPS pretest* results ($p=0.197$) and the *SIPS posttest* ($p=0.159$) in the comparison of the 3D-TND and SND groups.

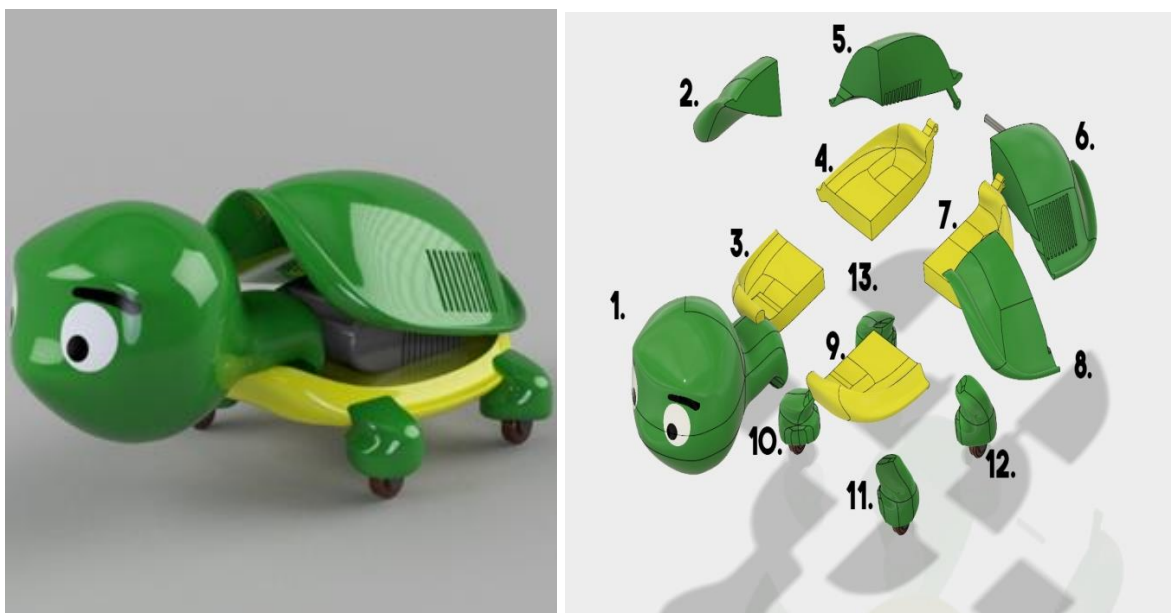


Figure 1. Therapeutic Nebulizer - model Fusion 360, parts.

Table 4. Mann-Whitney U Test Results of Intergroup Comparisons of Pre- and Posttest Scores

		Pretest			Posttest		
		Mean ± SD	Min	Max	Mean ± SD	Min	Max
PedsQ Healthcare Satisfaction Scale	Receiving information 3D-TND	72,22 ± 23,40	15,00	100	82,74 ± 17,51	25,00	100
	Receiving information SND	69,86 ± 18,69	2,00	100	69,66 ± 17,76	3,00	100
		Z = -,496 and p = ,062			Z = -3,432 and p = ,001**		
	Family Involvement 3D-TND	85,94 ± 14,71	37,50	100	89,87 ± 16,98	25,00	100
	Family Involvement SND	74,57 ± 18,25	25,00	100	72,77 ± 16,76	43,75	100
		Z = -3,032 and p = ,002***			Z = -4,736 and p = ,001**		
	Communication 3D-TND	77,77 ± 2,97	35,00	100	85,89 ± 17,96	25,00	100
	Communication SND	66,38 ± 19,34	25,00	100	64,05 ± 2,64	5,00	100
		Z = -2,523 and p = ,012***			Z = -1,555 and p = ,12		
	Technical Skills 3D-TND	83,52 ± 17,76	37,50	100	85,84 ± 21,83	,00	100
	Technical Skills SND	71,59 ± 19,01	<,001	100	67,94 ± 19,54	<,001	100
		Z = -3,234 and p = ,001**			Z = 4,486 and p = ,001**		
	Emotional Needs 3D-TND	71,23 ± 24,62	25,00	100	78,03 ± 25,53	,00	100
	Emotional Needs SND	56,59 ± 25,73	<,001	100	54,40 ± 27,04	<,001	100
		Z = -2,659 and p = ,008***			Z = -3,884 and p = ,001**		
	General Satisfaction 3D-TND	89,58 ± 13,82	41,67	100	92,80 ± 13,76	25,00	100
	General Satisfaction SND	73,86 ± 17,29	41,67	100	70,83 ± 18,28	41,67	100
		Z = -4,319 and p = ,001**			Z = -5,625 and p = ,001**		
SIPS	PedsQL Total 3D-TND	477,02 ± 98,13	221,67	600	511,62 ± 95,25	15,00	600
	PedsQL Total SND	411,58 ± 98,53	22,00	600	399,67 ± 101,87	228,33	600
		Z = -3,014 and p = ,003***			Z = -4,855 and p = ,001**		
	SIPS Total 3D-TND	27,34 ± 13,08	1	48	22,48 ± 13,64	,00	48
	SIPS Total SND	24,34 ± 1,27	7	48	25,09 ± 1,23	5,00	48
		Z = -1,291 and p = ,197			Z = -1,408 and p = ,159		

* Mann-Whitney U test, ** p < .001, *** p < .05

In the examination of the findings regarding the PedsQL Healthcare Satisfaction Scale, it was seen that the “*PedsQL pretest* scores ($p=0.003$) and *PedsQL posttest* scores ($p=0.001$) didn’t display a significance difference when the 3D-TND and SND groups were compared. A comparison was made of the 3D-TND and SND groups in terms of their pretest and posttest scores for the subscales of the PedsQL Healthcare Satisfaction scale. In the *PedsQL pretest*, it was found that when the 3D-TND and SND groups were compared, outside of the subscale Receiving Information, all dimensions displayed significant differences. In the *PedsQL posttest*, it was found that when the 3D-TND and SND groups were compared, all of the subscales showed significant differences.

DISCUSSION

Discussion of findings related to psychosocial symptoms

Inhalation therapy is a technique that is commonly used in children in the event of acute asthma attacks, bronchiolitis, bronchitis, pneumonia, cystic fibrosis and other similar respiratory system conditions (4,6,17). The devices employed in this treatment are commonly of the standard type, an apparatus that generates a loud sound and looks formidable to children. Being in the hospital for some medical condition and being exposed to unfamiliar surroundings and devices lead to the emergence of psychosocial symptoms in children (2,6). The results of this study show that treatment delivered with the 3D-TND produces fewer psychosocial symptoms than therapy with an SND. While children who receive therapy with an SND exhibit symptoms of crying, fearfulness or the desire to escape the treatment, it has been concluded that children’s psychosocial symptoms are reduced when 3D-TND therapy is implemented. A scan of the literature didn’t uncover any study that was conducted using a nebulizer based on 3D printing technology. The results of the study were therefore supported with the reports of only similar findings. Nijhof et al. (2018) reports a study that was carried out to provide educational support to hospitalized children willing to participate in the research for the purpose of reducing their psychosocial symptoms. It was concluded that participation in educational activities instigated a rise in the children’s favorable attitude toward the hospital, mitigated their fearfulness and allowed them to spend a more cheerful time at the hospital.

Yanık & Ayyıldız (2019) used a toy-type nebulizer device in children receiving nebulizer treatment and stated that anxiety and fear decreased significantly in children receiving treatment with a toy-type nebulizer. In the same study, it was concluded that crying and fear continued significantly in children receiving standard-type nebulizer treatment. In the study conducted by

Kırkan & Kahraman (2023), in which the fear and anxiety levels of children were evaluated using a toy nebulizer and a toy mask, it was concluded that there was a significant decrease in children's fear and anxiety.

Silva et al. (2020) examined the effect of therapeutic play and toy use on children's fear and anxiety in children receiving inhaler treatment. It was observed that fear and anxiety decreased significantly in children receiving inhaler treatment through therapeutic toys. In their study with a toy nebulizer device, Kırkan & Kahraman (2023) concluded that children who previously cried while receiving treatment did not cry while receiving treatment with the therapeutic device.

In a review of the literature, it was seen that Nijhof et al. (2018), Sağlık & Çağlar (2019), Silva et al. (2017) and Üstün et al. (2014) made use of various therapeutic approaches to reduce the adverse effects of illness and hospitalization on children. Sağlık & Çağlar (2019) used a picture-drawing method as a projective technique to reduce what appeared to be hospital-related symptoms in children and reported that feelings of fear, anxiety, depression and similar negative emotions were less frequent among the children (22-24). Stated that it was necessary for the sake of protecting pediatric health to make an early identification of any psychosocial symptoms hospitalized children may have. Toward this aim, the researchers developed an inventory to identify psychosocial symptoms that proved to determine psychosocial symptoms earlier than other measuring tools. It may be said that early identification of symptoms will allow for easier and earlier symptom management.

Discussion related to SIPS results

In the pretest-posttest comparisons of the 3D-TND and SND groups in this study, a significant difference was seen between the SIPS mean scores in the 3D-TND group but not in the SND group. In the comparison of the pretest and posttest mean scores in groups, however, no significant difference was observed between the SIPS mean scores. The common practice in the hospital of delivering medication via a nebulizer is seen to cause prevalent anxiety because of the appearance and sounds of the device (2,11,24). Kırkan & Kahraman (2023) found a significant difference in children's fear and anxiety after inhaler treatment with therapeutic play. Similar results are also seen in the studies conducted by Coşkuntürk & Gözen (2018) and Durak & Uysal (2021) (27,29).

Potasz et al. (2013) have devised games to reduce stress among hospitalized children with respiratory diseases. The authors found that toys and games can make the commonly

implemented nebulizer therapy much more tolerable for children, thereby increasing their compliance and reducing their stress. The study revealed that children adapted much more easily to hospital routines, clinical circumstances and devices with a toy type of nebulizer and that compared to children receiving therapy with a standard type of device, these children exhibited a lesser frequency of psychosocial symptoms.

Yanık and Ayyıldız (2018) examined the effect of using toy-type nebulizers on anxiety in children aged 3-6 and concluded that the use of toy-type nebulizers reduced anxiety in children. Jones et al. (2017) conducted a study in an effort to meet the needs of hospitalized children and their parents, working to determine their levels of anxiety and stress. According to the study, it was found that using child-friendly types of devices as well as tantalizing surroundings that address children during their stay at the hospital reduces stress and anxiety in both children and their parents.

Similar studies such as of Chen et al. (2014), Silva et al. (2017) and Suryawanshi et al. (2016) have studied the effects of therapeutic toys and games on anxiety, stress and fear levels of hospitalized children. The increase in adaptation to therapy and the reduced fear and anxiety found in these studies are similar. Ibfelt et al. (2015) and Paladino et al. (2014) studied the use of therapeutic toys by pediatric nurses. It was found that therapeutic toys diminished the use of medications among children and reduced anxiety, fear and other psychosocial symptoms. Studies in the literature reveal that hospitalized children suffer fear, anxiety and other psychosocial symptoms such as crying because of their experiences with their illness, being in a hospital, having to remain in unfamiliar surroundings, and undergoing medical treatment with various devices (20,25). The results of our study are consistent with what is reported in the literature.

Discussion of PedsQL Healthcare Satisfaction Scale results

When a child needs to be hospitalized, significant changes occur in the whole family's lifestyle. These changes cause all family members to experience fear, anxiety, stress, or crisis. Factors that cause these conditions include having anxiety about the child's recovery, being unfamiliar with the hospital environment, finding themselves useless in the care of the child, and feeling guilty. Parental satisfaction is defined in childcare as fulfilling the perceived positive expectations of the family (23,29,30).

Silva et al. (2017) and Teksoz et al. (2017) conducted a study in order to examine the fear, anxiety and healthcare satisfaction of parents of hospitalized children. They noted a high level of healthcare satisfaction among parents with children in the hospital who had been encouraged to adapt to treatment and provided education and increased communication by nurses. It was reported that when children were encouraged to participate in their own treatment and care, this resulted in higher parental healthcare satisfaction. In the study by Kapkin et al. (2020) and Teksoz et al. (2017) parents of hospitalized children were invited to participate in their child's care actively. The parents participated in feeding, dressing, diagnosing, treating, breathing exercises and steam applications, and it was observed that their healthcare satisfaction scores rose significantly, both in the overall scale and in all the subscales. This finding is consistent with the results of our study. Drayton et al. (2019) concluded that parents of children whose needs were met in the hospital were likely to have higher scores in terms of satisfaction with healthcare.

The literature acknowledges the importance of information for parents and their presence during interventions as this can reduce anxiety and increase parents' satisfaction with care (28-30). Specifically, although it has become common practice for parents to stay with their sick child in the hospital, most hospitals lack the routines and staff guidelines for involving parents in care processes and decisions (23,31). Studies that have worked with parents becoming involved in their child's care and treatment have indicated that parental stress, anxiety and other psychosocial symptoms are diminished and parental healthcare satisfaction increases.

Klinnert et al. (2008) conducted a study with parents of children hospitalized due to asthma treatment and found that parents' satisfaction and emotional states varied according to their children's reactions to the treatment process. Volerman et al. (2023) examined the satisfaction levels of parents of children hospitalized for asthma treatment. They found that the communication and satisfaction levels of parents of children without psychosocial symptoms during inhaler treatment were high. These findings are similar to the findings of our study.

Fisher & Broome (2011) report that parents who are included in the process of their children's treatment and care while in the hospital and are kept in the communication loop have increased satisfaction with the care provided. Cimke (2017) included families in the process of care given to children in their study and examined the satisfaction with care in both the child and the parents. They concluded that being at the child's side, being involved during postural drainage, breathing exercises and nebulizer therapy resulted in the parents' exhibiting markedly high

scores in terms of satisfaction with healthcare. In their examination of interventions carried out with the aid of creative games, Teksoz et al. (2017) found that this effort impacted satisfaction with care. The results of these studies in the literature are consistent with the outcome of our study.

CONCLUSIONS

With this study, we concluded that the 3D therapeutic nebulizer developed to reduce the psychosocial symptoms of children being administered nebulizer therapy was more effective in lessening these symptoms than the standard type of nebulizer machine. Using 3D printing technology in the effort to reduce the treatment-related psychosocial symptoms of sick and hospitalized children is an innovative approach that can be used.

Limitation

The inability to conduct the study at both hospitals also constituted one of its limitations. The study had to be conducted only in one institution because only one 3D-TND, which the researcher produced, was available. At the same time, the two hospitals were at an inconvenient distance from each other, and the device could obviously not be carried to the second institution while the treatment was ongoing in the first one. This situation constituted the limitation of the research.

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Conflict of interest

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