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The Effect of Therapeutic Touch on Functional Constipation in Infants and Young Children: A Randomized Controlled Study

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Abstract

Objective: The aim of this study was to determine the effect of therapeutic touch applied to infants and young children diagnosed with functional constipation according to the Rome IV criteria on constipation.

Materials and Methods: The study was conducted in a prospective, randomized controlled, parallel group (Experimental n = 30, Control n = 30) trial design. The study included 60 children aged between 6 and 24 months who applied to a hospital pediatric outpatient clinic with complaints of constipation and were diagnosed with functional constipation according to the Rome IV diagnostic criteria. The experimental group received a total of 12 therapeutic touch sessions, three times a week, in addition to routine care for 4 weeks. The control group received routine care. Data were collected using the "Child-Family Information Form" and the "Bristol Stool Scale."

Results: The descriptive characteristics of the experimental and control groups were found to be similar. A statistically significant difference was found between the experimental and control groups in terms of bowel sounds, stool number, stool density, and discomfort intensity ($p<0.05$) and the magnitude of the effect (group*time interaction) of the change was determined to be moderate. In addition, a significant difference was found between the experimental and control groups in the Bristol Stool Scale in the 2nd and 3rd weeks ($p<0.05$).

Conclusion: Therapeutic touch application was found to be effective in children with functional constipation by increasing bowel sounds and stool number, normalizing stool density, and reducing the intensity of discomfort during defecation.

Keywords infant · child · constipation · therapeutic touch

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INTRODUCTION

Functional constipation (FC) is a common functional gastrointestinal problem that affects the child's quality of life (1). It is defined as infrequent, hard, and painful defecation that causes distress to the family and the child. The prevalence of FC reported in infants and young children varies according to the diagnostic criteria among studies, but varies between 5% and 27% worldwide (1-3). FC is not the result of a structural or biochemical abnormality (1). FC in children is usually the result of holding back stool to avoid painful defecation (4). Bowel movements in infants and children usually occur daily. This behavior is thought to result from the inability to coordinate increased intra-abdominal pressure with the relaxation of the pelvic floor muscle. This condition improves as muscle coordination develops in children (1, 5). Constipation, which is among the functional gastrointestinal disorders, was previously diagnosed according to the Rome II and later Rome III criteria. However, it was updated again in 2016 and diagnosed according to the Rome IV criteria (2, 3, 6, 7). Although FC is not life-threatening, it significantly affects the quality of life among patients (8). Changes in the bowel movement pattern in children cause stress and distress to the child and the family. It starts as a simple complaint in childhood, but if left untreated, it can lead to serious problems that can negatively affect the child's growth and development (5, 9). In a study, it was observed that 10% of children with constipation complaints had growth and developmental delays (10). Therefore, the prevention and treatment of constipation in infants and children is important (9). There are two broad categories of treatment for FC: pharmacological and non-pharmacological (11). Although pharmacological treatments have limited therapeutic effects, they also have some important side effects. In addition, symptoms tend to recur after treatment (11, 12). Laxatives are commonly used to treat FC. Therefore, treating constipation is quite costly and there is not enough reliable data on this subject (4). This limitation of medical treatment has increased the interest in the use of nonpharmacological methods to reduce, prevent, and relieve constipation. There are studies in the literature using different nonpharmacological methods to manage constipation (4, 8, 13-15). In these studies, methods such as massage, aromatherapy, laxatives, reflexology and acupuncture were used in managing constipation in children (4, 8, 13-15). In these studies, we noticed that Therapeutic Touch (TT), which is thought to have some positive effects especially in newborns, infants and children, was not used in the management of constipation. TT is a safe application that can be applied to all age groups (16-18). However, the effects of TT in children with FC are unknown. This study was conducted to determine the effect of therapeutic touch applied to infants and children diagnosed with functional constipation according to the Rome IV criteria on constipation.

Hypotheses of the research

H1: Children with functional constipation who were treated with therapeutic touch had more bowel sounds than children who were treated with routine care.

H2: Children with functional constipation who were treated with therapeutic touch had more stool counts than children who were treated with routine care.

H3: Children with functional constipation who were treated with therapeutic touch had more normal Bristol Stool Scale defecation patterns than children who were treated with routine care.

H4: Children with functional constipation who were treated with therapeutic touch had lower restlessness during defecation than children who were treated with routine care.

MATERIALS AND METHODS

Design and Setting

This study was designed as a prospective, parallel group randomized controlled trial. The diagram of the study is given in Figure 1 of the CONSORT 2010 (Consolidated Standards of Reporting Trials) (19). The study protocol was registered prospectively in the Clinical Trial Registry of the U.S. National Institutes of Health (https://clinicaltrials.gov/, identifier: NCT06353841). The recruitment and data collection were conducted from May 2023 to December 2024.

Population and Participants

The study was conducted in the Pediatrics Outpatient Clinic of a state hospital with children diagnosed with FC according to the Rome IV diagnostic criteria by a pediatrician (2, 3). Children diagnosed with FC who met the inclusion criteria (children being between 6 and 24 months old, born at term, birth weight between 2500 and 4500 g, mothers being able to read, write and speak Turkish, and parents being willing to participate in the study) were enrolled in the study. Children with congenital anomalies, any chronic disease, cow's milk allergy, celiac disease, hypercalcemia, and hypothyroidism, secondary diseases causing constipation such as neurological diseases, and parents with verbal and written communication disabilities were excluded from the study. Exclusion criteria were determined as the emergence of a health problem in the child during the study, failure to continue at least one routine follow-up, and the mother's desire to withdraw from the study.

Sample Size

A power analysis was performed using the G*Power (v3.1.9.2) program to determine the number of children to be included in the study group (20). The sample of the study was conducted with two groups: experimental (receiving therapeutic touch) and control (receiving routine care). For analyses to be conducted between independent groups, the Type 1 error probability (α) is accepted as 0.05 (95%

confidence level), and the Type 2 error probability (β) is accepted as 0.10 (80% power level). The effect size (δ=1.01) was calculated using the standard deviations obtained from the publication titled "A Randomized Controlled Trial Examining the Effects of Reflexology on Children with Functional Constipation" (4). In line with this effect size, it was calculated that the minimum sample size required would be 56 children , 28 for each group. Considering possible case losses, the number of children to be included in the study was determined as 60, 30 in the experimental group and 30 in the control group.

Randomization and Allocation

The study sample was determined according to the inclusion and exclusion criteria. Those who met the sample selection criteria and approved the informed consent form were randomized into the research groups. In this study, a simple randomization method and blocking were used in assigning children to the experimental and control groups. The assignment of children to the groups was done by a statistician other than the researcher using a computer program. A table created by entering the total number of cases through the program with the randomization URL address https://www.randomizer.org was used and randomly assigned to the groups. Which letter would be the experimental or control groups was determined by lottery. The letter A was used for the experimental group and B for the control group.

A total of 82 children were evaluated in terms of compliance with the inclusion criteria. 22 children who did not meet the inclusion criteria were excluded from the study, and 60 children who met the criteria were enrolled in the study. The children were randomly assigned to the experimental (30) and control (30) groups. Four children who were separated did not participate in the evaluations from the 4th week and were subjected to ITT analysis (Figure 1).

Blinding

Participant and researcher blinding was not possible. Researchers were blinded in terms of determining the study groups, assignment, analysis, and reporting. In addition, data entry into the computer and extraction after the statistical process was completed were performed by someone other than the researchers.

Procedures

The researcher evaluated the compliance of children diagnosed with constipation by the physician with the sample selection criteria. After the mothers of children who met the sample selection criteria were informed about the study and informed consent was obtained, they filled out the "Child-Family Information Form" for the pre-test and the "Bristol Stool Scale" to evaluate the stool consistency of the children.

Routine Care

All children in the study group received routine care. The children were given a detailed history and physical examination by a pediatric specialist in the hospital to determine the diagnosis, signs and symptoms. During a complete physical examination, the baby's weight gain, nutrition, defecation patterns, fever and illness were questioned and monitored. Factors that could affect the baby's constipation were questioned. Routine care and treatment practices in children with constipation: first behavioral treatment (such as massage, exercise) and then the mother is questioned and given diet treatment, then the baby is given drug treatment.

Therapeutic Touch Application

The researcher has attended courses organized by the International Therapeutic Touch Association and is certified to be able to apply TT. As a result of the literature review, TT was accepted as the most appropriate time to apply TT to children, and the experimental group was applied TT once a day for 10 minutes at any time during the day for three consecutive days (16, 18, 21, 22).

In the Therapeutic Touch application,

- The child and his mother were taken to the baby's room.
- The child's mother was explained the application.
- The researcher washed her hands and brought them to body temperature by rubbing them together.
- The child was laid down on a clean bed with her mother in her clothes so that she could make a close and comfortable eye contact.
- It was applied to the child's entire body by touching it with the practitioner's palms or from a distance of approximately 2 cm.
- The hands were moved parallel to the feet from the body level.
- TT was applied to the child's head and abdomen.
- The application was made by touching the child's forehead for approximately 2 min to facilitate sleep.
- The application was made especially to the child's abdomen, which was a problem, for approximately three minutes.
- The child's response to the application was observed.

Experimental Group

All children in this group received the routine treatment recommended by the polyclinic physician for constipation. In addition to this treatment, TT was applied. The children and their mothers, who would form the experimental group, were invited to the hospital's baby room for three consecutive days. TT was applied for three consecutive days, followed by a four-day break. TT was applied again for three consecutive days the following week, followed by a four-day break and lasted for four weeks. The mother, child and the

researcher were present in the baby room. In the first encounter, the researcher applied TT for an average of ten minutes during the day. For the next two days, ten minutes of TT was applied in the hospital baby room at any time during the day. The children were evaluated once a week for constipation. The children's weight, abdominal circumference, bowel sounds, stool count, and stool density were recorded weekly. Constipation anxiety was introduced to the mothers. The children's "Bristol Stool Scale" and "constipation anxiety intensity" were recorded weekly. All the experimental group children were followed up for four weeks. No adverse effects occurred in the babies during and after TT application.

Control Group

The children received the routine treatment recommended by the polyclinic physician for constipation. Apart from this, no method was applied by the researcher. The children and their mothers, who would form the control group, were invited to the hospital baby room weekly. The mother, child, and the researcher were present in the baby room. The mothers used their normal coping methods. TT was not applied. The children were evaluated once a week for constipation. The children's weight, abdominal circumference, bowel sounds, stool count, and stool density were recorded weekly. Constipation discomfort was introduced to mothers. Children's "Bristol Stool Scale" and "constipation discomfort intensity" were recorded weekly. All control group children were followed up for 4 weeks.

Measures

The research data were collected using the "Child-Family Information Form," which includes a "monitoring form" for monitoring weight, abdominal circumference, bowel sounds, stool count, stool density and restlessness intensity, and the "Bristol Stool Scale" to assess children's stool consistency.

Child-Family Information Form

The child-family information form was prepared by researchers in line with the literature (2,4,5,8,9,11,13-15,23). The form included 22 questions to obtain information such as sociodemographic information about the child and family and the child's nutritional and defecation characteristics. The follow-up form is a four-week follow-up form prepared by researchers, in which the children's weekly body weight (g), abdominal circumference (cm), bowel sounds (min), stool number, stool density, and child restlessness are recorded. The child's level of restlessness was assessed between 0 and 3 points ("0" means no crying or grimacing, "1" means mild crying and mild grimacing, "2" means moderate crying and grimacing, "3" means hysterical intense crying and grimacing) (8).

Bristol Stool Scale (BSS)

The Bristol Stool Scale Form, developed in 1997, was used to assess the stool consistency of the children included in the study. In this scoring system, stool hardness was divided into seven classes, from the hardest to the softest, according to the adhesion and surface cracking characteristics of the stool (24, 25). Type 1 and Type 2 were hard stool types and indicated the presence of constipation, Type 3, Type 4 and Type 5 indicated normal stool, and Type 6 and Type 7 indicated diarrhea (24-26).

Statistical Analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS Inc., Chicago, IL, USA) version 23.0 for Windows program. Kolmogorov-Smirnov and Shapiro-Wilk tests were used to determine the suitability of the data for normal distribution. Data are presented as frequency, percentage, mean±s.deviation (SD). The Pearson chi-square test was used to compare categorical variables according to groups. Mann–Whitney U and independent-sample t tests were used to compare data according to groups. Repeated analysis of variance was used to compare data according to three or more time periods. The Bonferroni correction was used for multiple comparisons. The intention-to-treat (ITT) analysis was performed to complete the missing data (27). The Last Observation Carried Forward method was used (28) where data were missing. Statistical significance level was set as $p<0.05$. Groups: Partial eta squared (η_p^2) was calculated in the evaluation of effect size using two-way MANOVA analysis in repeated measures in terms of group, time, and group*time interaction. In the evaluation of the partial eta squared, was accepted as 0.01 as small, 0.06 as medium, and 0.14 as large (29).

Ethical Considerations

This study was approved by the Necmettin Erbakan Üniversitesi Health Sciences Scientific Research Ethics Committee with 03.05.2023 date 2023/43 number (IRB numbered:2023/435; Dated:) ethics committee. To collect the research data, the institution permission was approved by the Burdur Provincial Health Directorate and Necmettin Erbakan Üniversitesi Hemşirelik Hospital Chief Physician Board. The study was compiled according to the Declaration of Helsinki. Before starting the research, the purpose, duration, plan of the research, and how the collected data would be used were explained to the mothers of all children through the "Informed Voluntary Consent Form" and their verbal and written permissions were obtained. In addition, at the end of the research, TT was applied to the children in the control group whose parents accepted after the final tests in accordance with research ethics.

RESULT

The descriptive characteristics of the children participating in the study and their comparisons between the groups are shown in

Table 1. It was found that there was no significant difference in the descriptive characteristics between the experimental and control groups (p≥0.05) and the groups were homogeneous (Table 1).

Table 1. Comparison of descriptive characteristics according to the groups

Characteristics	Experimental Group (n = 30)	Control Group (n=30)		
	Mean±SD	**Mean±SD**	**U**	**p**
Child age (months)	13.07±4.20	12.93±4.93	416.000	0.613
Mother's age	28.63±4.03	28.10±3.82	418.500	0.640
	n (%)	**n (%)**	**χ^2**	**p**
Child's gender				
Girl	13 (43.3)	16 (53.3)	0.601	0.438
Boy	17 (56.7)	14 (46.7)		
Gestational age (weeks)				
38	8 (26.7)	3 (10.0)		
39	11 (36.7)	14 (46.7)	9.196	0.06
40	11 (33.6)	13 (43.3)		
Mother's education status				
Middle School	4 (13.3)	2 (6.7)		
High School	20 (66.7)	23 (76.7)	0.967	0.617
University	6 (20.0)	5 (16.7)		
Mother's employment status				
Yes	9 (30.0)	6 (20.0)	0.800	0.371
No	21 (70.0)	24 (80.0)		
Family type				
Extended	3 (10.0)	2 (93.3)	0.218	0.640
Nuclear	27 (90.0)	28 (6.7)		
Person taking care of the child				
Herself	22 (73.3)	23 (76.7)	0.165	0.921
Other	8 (26.7)	7 (23.3)		
Use of supplementary food				
Yes	30 (100)	30 (100)	—	1,000[F]
No	0	0		
Child Nutrition				
Natural	0	0		
Mixed	30 (100)	30 (100)	—	1,000[F]
Artificial	0	0		
Using formula				
Yes	0	0	—	1,000[F]
No	30 (100)	30 (100)		
Taking cow's milk				
Yes	2 (6.7))	1 (3.3)	0.351	0.554
No	28 (93.3)	29 (96.7)		
Diaper stool status				
Yes	21 (73.3)	22 (73.3)		
Sometimes	6 (20.0)	5 (46.7)	0.114	0.945
No	3 (7.7)	3 (10.0)		
Stool density				
Hard	21 (70.0)	17 (56.7)		
Normal	7 (23.3)	8 (26.7)	1.773	0.412
Soft	2 (6.7)	5 (16.6)		
Constipation				
Yes	30 (100)	30 (100)	—	1,000[F]
No	0	0		
Defecation blood				
Yes	0	0	—	1,000[F]
No	30 (100)	30 (100)		
Restlessness during stool				
Yes	30 (100)	30 (100)	—	1,000[F]
No	0	0		
Nausea and vomiting				
Yes	0	0	—	1,000[F]
No	30 (100)	30 (100)		
	Mean±SD	**Mean±SD**	**U**	**p**
Duration of breastfeeding	12.83±3.73	12.89±4.79	421.500	0.672
Time to start complementary feeding	5.63±0.85	5.76±0.78	480.500	0.590
Number of vegetables per day	1.03±0.41	1.06±0.44	464.000	0.759
Number of fruits per day	2.16±0.53	1.90±0.84	363.000	0.161
Number of yogurts per day	1.06±0.25	1.10±0.30	465.000	0.643
Number of stools per week	1.60±0.97	1.90±0.84	566.000	0.07
Duration of the constipation complaint	1.26±0.58	1.50±0.68	537.000	0.110

U: Mann-Whitney U test;
χ^2: Pearson chi-square test;
n (%); SD: standard deviation; p<0.05.

The distribution and comparison of the weight, abdominal circumference, bowel sounds, and stool count of all groups within and between the groups in the follow-ups (1st day, 1st, 2nd, 3rd, and 4th weeks) and change depending on time (group*time interaction) are shown in Table 2.

When the groups were compared, there was no statistical difference between the weights in all follow-ups and they were found to be similar (p≥0.05). It was found that the weight averages of the experimental and control groups (group effect) were different (F=55.775; η_p^2=0.490; p<0.001). However, when the weight averages were examined according to time (time effect), it was determined that there was no statistically significant difference in the weight averages of the experimental and control group children (F=0.436; η_p^2=0.007; p=0.664). When the joint effect of group and time on weight (group*time interaction) was examined, it was determined that there was no significant difference in the group*time interaction (F=0.046; η_p^2=0.001; p=0.831) (Table 2).

Table 2. Comparison of the outcomes of children according to groups and time-related change (Group×Time Interaction)

Outcomes	Groups		t	p	η_p^2	%95 CI	
	Experimental Mean±SD	Control Mean±SD					
Weight (gr)							
First day	10196.36±1366.82	10138.86±1529.07	0.154	0.878	0.000	−692.03	807.03
1. week	10286.00±1386.51	10223.83±1517.38	0.166	0.869	0.000	−689.02	813.35
2. week	10363.66±1389.71	10272.16±1511.96	0.244	0.808	0.001	−659.02	842.02
3. week	10410.83±1395.33	10318.83±1499.79	0.246	0.807	0.001	−656.64	840.64
4. week	10495.33±1397.50	10397.83±1482.86	0.262	0.794	0.001	−647.17	842.17
Abdominal circumference							
First day	47.66±2.68	47.50±2.81	0.235	0.815	0.001	−1.25	1.58
1. week	47.80±2.56	48.07±2.74	−0.389	0.699	0.003	−1.64	1.10
2. week	48.06±2.53	49.13±2.52	−1.633	0.108	0.044	−2.37	0.24
3. week	48.23±2.44	49.80±2.20	−2.607	**0.012**	0.105	−2.76	−0.36
4. week	48.40±2.42	50.16±1.91	−3.129	**0.003**	0.144	−2.89	−0.63
Bowel sounds							
First day	2.87±1.56	2.63±1.69	0.554	0.582	0.005	−0.61	1.07
1. week	3.26±1.36	3.10±1.47	0.455	0.651	0.004	−0.56	0.89
2. week	4.43±1.27	3.40±1.40	2.981	**0.004**	0.133	0.33	1.72
3. week	6.87±2.50	4.20±1.37	5.117	**0.000**	0.311	1.62	3.70
4. week	7.53±2.38	5.13±0.97	5.096	**0.000**	0.309	1.45	3.35
Number of stools							
First day	1.60±0.97	2.00±0.87	−1.682	0.098	0.047	−0.87	0.07
1. week	2.10±0.80	2.16±0.83	−0.315	0.754	0.002	−0.48	0.35
2. week	2.97±0.72	2.76±0.86	0.979	0.332	0.016	−0.20	0.61
3. week	3.66±0.76	3.00±0.74	3.440	**0.001**	0.169	0.27	1.05
4. week	4.37±1.09	3.86±1.10	1.757	0.084	0.051	−0.69	1.06

	Weight			Abdominal circumference			Bowel sounds			Number of stools		
	F	p	η_p^2	F	P	η_p^2	F	p	η_p^2	F	p	η_p^2
Group	55.775	0.000	0.490	82.274	0.000	0.587	171.974	0.000	0.748	160.543	0.000	0.735
Time	0.436	0.664	0.007	27.707	0.000	0.323	25.366	0.000	0.304	8.562	0.000	0.129
Group×Time interaction	0.046	0.831	0.001	2.045	0.000	0.034	11.979	0.001	0.171	0.923	0.000	0.016

t: independent-sample t-test;
F:two-way MANOVA test;
SD: standard deviation;
η_p^2:Partial eta squared; *p<.001.

There was no statistical difference between the abdominal circumference measurements of the groups on the 1st day, 1st, 2nd, 3rd, and 4th weeks and they were found to be similar (p≥0.05). It was determined that the mean abdominal circumferences of the children in the experimental group in the 3rd and 4th weeks were lower than those in the control group, and the difference was statistically significant (p<0.05). It was found that the mean abdominal circumferences of the children in the experimental and control groups (group effect) were different (F=82.274; η_p^2=0.587; p<0.001). The difference in the abdominal circumference (time effect) of the children in the experimental group was found to be statistically significant (F=27.707; η_p^2=0.323; p<0.001). When the joint effect of group and time on abdominal circumference (group*time interaction) was examined, it was determined that there was a significant difference in the group*time interaction and the effect size was medium (F=2.045; η_p^2=0.034; p<0.001) (Table 2). There was no statistical difference between the bowel sounds of the groups on the 1st day and the 1st week and it was found to be similar (p≥0.05). It was determined that the mean bowel sounds of the children in the experimental group at the 2nd, 3rd, and 4th weeks were higher than those in the control group, and the difference was statistically significant (p<0.05). It was found that the mean bowel sounds of the children in the experimental and control groups (group effect) were different (F=171.974; η_p^2=0.748; p<0.001). It was determined that the bowel sounds of the children in the experimental group increased over time (time effect), and the difference was statistically significant (F=25.366; η_p^2=0.304; p<0.001). When the joint effect of group and time on bowel sounds (group*time interaction) was examined, it was found that there was a significant difference in the group*time interaction and that the bowel sounds of the experimental group increased significantly over time. The effect size was determined to be large (F=11.979; η_p^2=0.171; p<0.001) (Table 2). These results support the H1 hypothesis.

There was no statistical difference between the number of stools between the groups on the 1st day, 1st, 2nd, 3rd, and 4th weeks and they were found to be similar (p≥0.05). It was determined that the average number of stools in the 3rd week of the children in the experimental group was higher than those in the control group, and the difference was statistically significant (p <0.05). It was determined that the mean number of stools of children in the experimental and control groups (group effect) were different (F=160.543; η_p^2=0.735; p<0.001). It was determined that the number of stools of the children in the experimental group increased over time (time effect), and the difference was statistically significant (F = 8.562; η_p^2= 0.129; p < 0.001). When the joint effect of group and time on the number of stools (group*time interaction) was examined, it was found that there was a significant difference in the group*time interaction and the number of stools in the experimental group increased significantly according to time. The effect size was found to be small (F=11.979; η_p^2=0.171; p<0.001) (Table 2). Accordingly, the H2 hypothesis was supported.

Table 3 shows the distribution of stool density in all groups (1st day, 1st, 2nd, 3rd, and 4th weeks) during the follow-up of the children within the group and between the groups. It was found that the distribution of stool density of the experimental and control groups was similar on the 1st day, 1st, 2nd, 3rd, and 4th weeks. When the groups were compared, it was determined that there was no statistically significant difference. However, it was found that there was a significant difference between the groups in the stool density of the children in the 3rd week (χ^2=4.444; p=0.035). It was found that the stool density of the experimental group children was soft in n = 22 (73.3%) and the control group children was soft in n = 14 (46.7%) (Table 3).

Table 3. Comparison of the stool density of children according to the groups

Stool density	Experimental Group	Control Group	χ^2	p
	n (%)	n (%)		
First Day				
Hard	21 (70.0)	19 (63.3)		
Normal	7 (23.3)	8 (26.7)	1.773	0.412
Soft	2 (6.7)	5 (10.0)		
1. week				
Hard	19 (63.3)	17 (56.7)		
Normal	8 (26.7)	8 (26.7)	0.611	0.737
Soft	3 (10.0)	5 (16.6)		
2. week				
Hard	4 (13.3)	9 (30.0)		
Normal	17 (56.7)	11 (36.7)	3.261	0.196
Soft	9 (30.0)	10 (33.3)		
3. week				
Hard	0	0		
Normal	8 (26.7)	16 (53.3)	4.444	**0.035**
Soft	22 (73.3)	14 (46.7)		
4. week				
Hard	0	0		
Normal	4 (13.3)	7 (23.3)	1.002	0.317
Soft	26 (86.7)	23 (76.7)		

χ^2: Pearson chi-square test;
n (%); p<0.05.

Table 4. Comparison of the Bristol Stool Scale of children according to the groups

Bristol Stool Scale	Experimental Group	Control Group	χ^2	p
	n (%)	n (%)		
First Day				
Type 1 (Extremely Constipated)	19 (63.3)	16 (53.3)	2.057	0.358
Type 2 (mildly constipated)	10 (33.3)	10 (33.3)		
Type 3 (Normal)	1 (3.4)	4 (13.4)		
Type 4 (Normal)	0	0		
1. week				
Type 1 (Extremely Constipated)	13 (43.3)	18 (60.0)	2.586	0.274
Type 2 (mildly constipated)	14 (46.7)	8 (26.7)		
Type 3 (Normal)	3 (10.0)	4 (13.3)		
Type 4 (Normal)	0	0		
2. week				
Type 1 (Extremely Constipated)	3 (10.0)	9 (30.0)	9.104	**0.028**
Type 2 (mildly constipated)	13 (43.3)	14 (46.7)		
Type 3 (Normal)	8 (26.7)	7 (23.3)		
Type 4 (Normal)	6 (20.0)	0 (0)		
3. week				
Type 1 (Extremely Constipated)	0	0	6.947	**0.031**
Type 2 (mildly constipated)	9 (30.0)	16 (53.3)		
Type 3 (Normal)	8 (26.7)	10 (33.3)		
Type 4 (Normal)	13 (43.3)	4 (13.4)		
4. week				
Type 1 (Extremely Constipated)	0	0	4.202	0.122
Type 2 (mildly constipated)	2 (6.7)	7 (23.4)		
Type 3 (Normal)	12 (40.0)	13 (43.3)		
Type 4 (Normal)	16 (53.3)	10 (33.3)		

χ^2: Pearson chi-square test;
n (%); p<0.05.

Table 4 shows the distribution of the Bristol Stool Scale (1st day, 1st, 2nd, 3rd, and 4th weeks) within and between groups in all groups during the follow-up of the children. The Bristol Stool Scale distributions of the experimental and control groups were found to be similar on the first day, 1st and 4th weeks. When the groups were compared, it was determined that there was no statistically significant difference. However, it was found that there was a significant difference between the groups in the Bristol Stool Scale of the children in the 2nd and 3rd weeks (p<0.05). The Bristol Stool Scale distributions of the children at the 2nd week were as follows: In the experimental group, n = 3 (10%) were Type 1 severely constipated, n = 13 (43.3%) were Type 2 mildly constipated, n = 8 (26.7%) were Type 3 normal, n = 6 (20%) were Type 4 normal, and in the control group, n = 9 (30%) were Type 1 severely constipated, n = 14 (46.7%) were Type 2 mildly constipated, n = 7 (23.3%) were Type 3 normal. The Bristol Stool Scale distributions of the children in the 3rd week were as follows: In the experimental group, n = 9 (30%) were Type 2 mild constipation, n = 8 (26.7%) were Type 3 normal, n = 13 (43.3%) were Type 4 normal, and n = 16 (53.3%) in the control group were Type 2 mild constipation, n = 10 (33.3%) were Type 3 normal, and n = 4 (13.4%) were Type 4 normal (Table 4). These results support the H3 hypothesis.

The distribution and comparison of the intensity of restlessness during defecation of the children in the follow-ups (1st day, 1st, 2nd, 3rd, and 4th weeks) according to the within-group and between-group changes over time (group*time interaction) are shown in Table 5. There was no statistically significant difference in the intensity of restlessness during defecation between the groups on the 1st day and it was found to be similar (p≥0.05). It was determined that the restlessness intensity averages of the children in the experimental group were lower than those in the control group in the 1st, 2nd, 3rd, and 4th weeks, and the difference was statistically significant (p<0.05). It was determined that the restlessness intensity averages of the children in the experimental and control groups (group effect) were different (F=77.754; η_p^2=0.573; p<0.001). It was determined that the anxiety intensity of the children in the experimental group relaxed over time (time effect), and the difference was statistically significant (F=4.731, η_p^2=0.075; p<0.001). When the joint effect of group and time on anxiety intensity (group*time interaction) was examined, it was found that there was a significant difference in the group*time interaction and that the anxiety intensity of the experimental group relaxed significantly over time. The effect size was determined to be large (F=7.774; η_p^2=0.118; p<0.001) (Table 5). These results support the H4 hypothesis.

Table 5. Comparison of the intensity of restlessness during defecation of children according to groups and time-related change (Group×Time Interaction)

Intensity of the child's restlessness in defecation	Groups		t	p	η_p^2	%95 CI	
	Experimental Group Mean±SD	Control Group Mean±SD					
First day	1.70±0.46	1.71±0.48	0.000	1.000	0.000	−0.24	0.24
1. week	1.69±0.47	1.83±0.37	−1.216	**0.016**	0.025	−0.35	0.08
2. week	1.33±0.71	1.73±0.45	−2.604	**0.012**	0.105	−0.70	−0.09
3. week	0.74±0.83	1.36±0.72	−3.165	**0.002**	0.147	−1.03	−0.23
4. week	0.30±0.59	0.76±0.81	−2.527	**0.014**	0.099	−0.83	−0.09

	Intensity of the child's restlessness		
	F	p	η_p^2
Group	77.754	**0.000***	0.573
Time	4.731	**0.007***	0.075
Group × Time interaction	7.774	**0.006***	0.118

t: independent-sample t-test;
F: two-way MANOVA test;
SD: standard deviation;
η_p^2: Partial eta squared;
*p<.001

DISCUSSION

This study is important because it is the first randomized controlled trial to confirm the effectiveness of TT application on constipation [weight (g), abdominal circumference (cm), bowel sounds (min), number of stools, stool density, child's restlessness intensity, Bristol Stool Scale] in infants and young children aged 6-24 months, diagnosed with FC according to Rome IV diagnostic criteria, in three weekly sessions for a total of four weeks. TT showed that the results of the study increased the number of bowel sounds and stools by the second week, normalized stool density by the second week, and softened it by the third week.

It was determined that 59.5% of the children had previously used medication for constipation, 5.4% had a special diet, and 13.5% had received motivational training; however, the problem had continued for an average of 24 months. Similar studies conducted in Türkiye reported that the duration of constipation was very long (4, 10). There is a need for evidence on the use of complementary health approaches to reduce FC in children who do not receive sufficient positive responses with conventional medical treatment (3, 4). Nurses and parents use nonpharmacological methods to reduce and prevent FC (30, 31). TT application is reported to be effective and safe in reducing pain, anxiety, and infantile colic in infants and children (16, 18). However, no study has examined the effects of TT on FC. There are studies showing the effectiveness of other complementary therapies in FC (4, 30-32). Since no other study examined the effect of TT in children with FC, the findings were discussed by comparing them with the results of studies using other methods.

In the literature, similar effects have been shown in studies where different methods were applied to prevent and eliminate FC in children (4, 31, 33). In one study, one group of children received standard care and the other group received standard care plus visceral manipulation for four weeks, and painful defecation, stool consistency, defecation frequency, and the effects were evaluated before and after the treatment period using the Pain Rating Scale, Bristol stool form scale, and patient/parent report (30). In another study, one group of children received aromatherapy massage, one group received normal abdominal massage, and the other group was compared as a control group. Children were evaluated for gas frequency, crying duration, and mothers' anxiety levels before the massage, two weeks later, and four weeks later (31). Another study examined the effectiveness of reflexology applied for 10 minutes per day, five days per week, for four weeks, and the children's defecation characteristics, stool count and density were monitored for four weeks (4). In this study, TT was applied to the experimental group for 12 sessions, three days per week, for four weeks, and the children were followed up weekly.

The bowel sounds of the children in the experimental group were significantly higher than those in the control group from the second week, and the stool count was significantly higher from the third week ($p<0.05$). The change between the groups was found to be statistically significantly different and at a medium effect level. The stool density of the children in the experimental group was normal from the second week and soft from the third week ($p<0.05$) compared to the control group. Similarly, Zakaryaei et al. (30) compared the effectiveness of visceral manipulation in children with FC, and the stool frequency increased significantly compared to the control group. In another study, Canbulat and Bal (4) observed an improvement in the stool density of the children with FC, to whom they applied reflexology five times per week for four weeks, starting from the second week. There was a difference between the experimental and control groups, although it was not significant in the first week. In another study, Karaaslan and Arıkan (31) compared the effectiveness of arometapy and normal massage, and the frequency of gas was statistically significantly different and higher after 2 and 4 weeks compared to the control group. As in this study, it was determined that the number of stools and bowel sounds of children increased after two weeks.

The Bristol Stool Scale showed its effect in the first week compared to the control group in the children in the experimental group, but no difference was found in the first week. The Bristol Stool Scale in the second and third week follow-ups of the children in the experimental group was found to be significantly different from the control group ($p<0.05$). Zakaryaei et al. (30) compared the effectiveness of visceral manipulation in children with FC in their study, in which they compared the Bristol Stool Scale to the control group, but the normal stool density in the experimental group was significantly higher than that in the control group. In this study, the Bristol Stool Scale was statistically more normal in the second and third weeks. However, although it was not statistically different in the fourth week, the Bristol Stool Scale normal level of the children in the experimental group was seen to be higher.

The intensity of restlessness during defecation in the children in the experimental group compared to the control group decreased significantly as of the first week ($p<0.05$). The effect size was seen to be large.

Liu et al., in their meta-analysis study examining the effectiveness of massage for treating FC in infants, found that massage had a high effect and was statistically significant. Massage is truly superior to drug therapy alone for treating infant FC (32). Nam et al. demonstrated that aromatherapy application can be an effective experimental in relieving constipation (34). Lai et al. demonstrated that aromatherapy application improves bowel movements and significantly increases the quality of life (35). Bishop et al. found that foot reflexology is an effective method in treating encopresis and constipation (36). Although different interventions were applied to children with FC, the evaluation characteristics were generally similar. In general, although there are methodological differences in

these studies, the characteristics associated with FC support each other. Even light touch can affect FC symptoms by activating the parasympathetic nervous system of children (37). In this study, the parent was included by providing eye-to-eye contact with the child. Child-mother interaction was supported.

Study Limitations

The study results cannot be generalized to Türkiye because this study was conducted in a single center and the results were limited to the study group, limiting the generalizability.

CONCLUSIONS

As a result, a total of 12 TT sessions, three times a week in addition to routine care for four weeks, were found to be effective in reducing FC symptoms. This study showed positive results from TT and determined that it is an effective and safe method for reducing constipation. A contribution was made to the use of an inexpensive and effective nonpharmacological method to increase children's peace. A contribution was made to the development of the nursing care approach at the national and international levels. In addition, it is thought to contribute to nursing practices as it is a new and alternative method that can be used in infants and children to reduce FC. The use of an effective theoretical framework in predicting the behaviors of infants and young children by mothers with constipated children has been useful in guiding initiatives encouraging the use of methods in reducing constipation symptoms. Since TT is an easily applicable, economical, safe and effective method, it can be integrated into pediatric clinics, family health center nurses, health services and undergraduate/graduate nursing curricula. Based on the results obtained in the current study, we recommend further studies comparing larger sample groups using different methods and monitoring them for longer periods of time.

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Informed Consent	Written consent was obtained from the participants.
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