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ORIGINAL ARTICLE

The Effect of Foot Bath and Massage on Chemotherapy-Induced Nausea and Vomiting in Pediatric Hematology-Oncology Patients: A Randomized Controlled Study

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OBJECTIVE

This study aimed to evaluate the effect of foot bath and massage on chemotherapy-induced nausea and vomiting in pediatric hematology-oncology patients.

METHODS

This research was designed as a randomized controlled study. The population consisted of children aged 8–18 years who were receiving chemotherapy and being followed in the pediatric hematology and oncology clinic and outpatient clinic of the University Faculty of Medicine Children's Hospital between December 2022 and December 2023. Using a computer-generated randomization scheme created by Randomization.com, the children were assigned to either the intervention or control group. The sample size was calculated using a power analysis program, which determined that 15 children per group, for a total of 30 participants, were required. Data were collected using the Child Information Form and the Baxter Retching Faces Scale (BARF). Children in the intervention group received a 20-min foot bath that began 5 min before the initiation of chemotherapy following premedication and continued during the first 15 min of chemotherapy. The control group did not receive a foot bath. The BARF scale was administered to both groups before chemotherapy and at the 15th min of chemotherapy.

RESULTS

No statistically significant difference was found between the intervention and control groups in the mean BARF scores at the 15th min of chemotherapy ($p>0.05$).

CONCLUSION

Although the difference between the intervention and control groups in mean BARF scores at the 15th min of chemotherapy was not statistically significant, the intervention group demonstrated lower BARF scores compared to the control group.

Keywords: Chemotherapy; foot bath; foot massage; nausea; pediatrics; vomiting.
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INTRODUCTION

Cancer is one of the leading causes of death among children and adolescents. It is estimated that each year, 400.000 children and adolescents aged 0–19 years are diagnosed with cancer. The most common types of childhood cancers include leukemias, brain tumors, lymphomas, neuroblastoma, and Wilms tumor. At the same time, more than 80% of children with cancer in high-income countries receive treatment due to access to comprehensive healthcare services, < 30% of children in low- and middle-income countries are treated. Standard cancer treatments include chemotherapy, surgery, and radiotherapy.[1]

Children with cancer experience numerous symptoms related to diagnosis and treatment, which significantly affect their daily lives.[2] These symptoms include fatigue, hair loss, nausea, vomiting, loss of appetite, anxiety, pain, insomnia, restlessness, diarrhea, constipation, weight loss, exhaustion, taste changes, mucositis, numbness in the hands and feet, and dry mouth.[3] Chemotherapy-induced nausea and vomiting (CINV) are among the most common acute morbidities observed in children undergoing cancer treatment and have a considerable impact on their quality of life.[4] One study reported that 60.9% of hospitalized children receiving chemotherapy experienced nausea and 41.3% experienced vomiting.[3] Another study found that nausea and vomiting were more prevalent among children aged 10–12 years (nausea: 14%, vomiting: 56%) compared to those aged 13–15 years (nausea: 10%, vomiting: 39%) and 16–18 years (nausea: 10%, vomiting: 19%).[2]

Symptoms such as nausea and vomiting impair children's physical, mental, and social functioning, negatively affect prognosis, lead to delays or limitations in treatment, and cause emotional distress.[2] Although CINV is among the two most frequently reported symptoms by children with cancer, pharmacological management alone is not sufficient.[5] More than 40% of children continue to experience nausea and vomiting despite receiving antiemetic treatment.[5] Although progress has been made in antiemetic prophylaxis over the last two decades, only a limited number of pediatric chemotherapy agents have well-established emetogenic risk profiles.[4] Consequently, the increasing preference of families for complementary and alternative therapies (CAT) highlights the need for further research in this area.[4] When properly applied, CAT can enhance the effectiveness of antiemetic medications, reduce symptom burden during cancer treatment, and improve overall well-being and quality of life in children.[5]

Several studies have evaluated the effectiveness of different CAT modalities in controlling nausea and vomiting during cancer treatment.[5] Among children with cancer, commonly used CAT approaches include acupuncture, hypnotherapy,[5,6] acupressure, creative arts therapy,[5] aromatherapy,[5,7] foot massage, and reflexology.[7] However, uncertainty remains regarding which CAT method is most effective in preventing or reducing nausea and vomiting during and after cancer treatment.[5] Some studies have shown that both foot massage and foot reflexology are effective in reducing CINV, yet evidence on how children can specifically benefit from these interventions remains limited.[7]

Therefore, the aim of this study was to evaluate the effect of foot bath and massage on CINV in pediatric hematology-oncology patients.

Hypothesis

H1: Foot bath and massage reduce CINV in pediatric hematology-oncology patients.

MATERIALS AND METHODS

Study Design

This study was conducted as a randomized controlled trial.

Study Setting

The research was carried out in the pediatric hematology and oncology inpatient and outpatient clinic of the University Children's Hospital.

Measures and Tools

Data were collected using the Child Information Form and the Baxter Retching Faces Scale (BARF).

Child Information Form

The Child Information Form was developed by the researchers based on a review of the literature.[8–19] The form consists of two sections: Sociodemographic characteristics (two items) and disease-related characteristics (six items).

BARF

The BARF scale was developed by Baxter et al.[20] to evaluate nausea and vomiting among children aged 7–18 years presenting to pediatric day-surgery and emergency departments with vomiting complaints. The Turkish validity and reliability study was conducted by Şişman et al.[21] among children aged 7–18 years to assess post-operative nausea and vomiting.

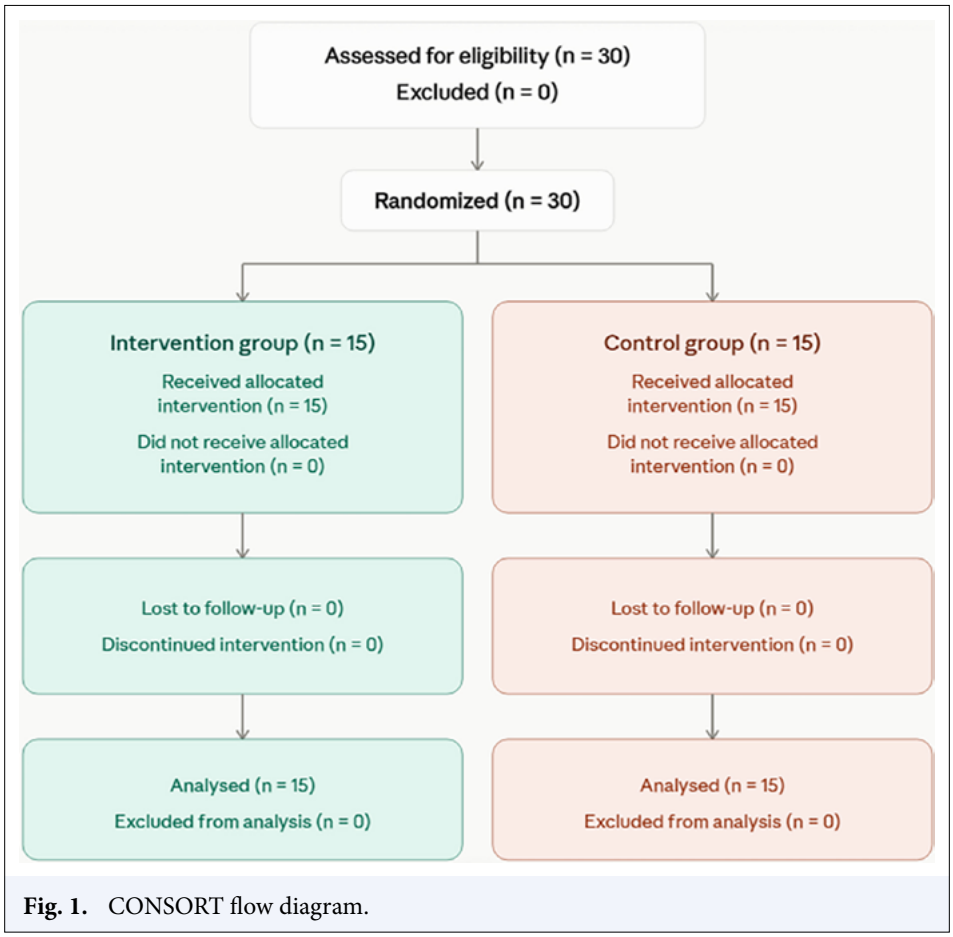


Fig. 1. CONSORT flow diagram.

The original scale demonstrated strong reliability (Spearman correlation coefficient=0.93; BARF score p=0.20), and the Turkish version was also found to be valid and reliable (Cochran's Q=9; p=0.437). The scale consists of six faces illustrating expressions ranging from "no nausea" to "vomiting," scored between 0 and 10. The leftmost face represents "no nausea" (0 points), whereas the rightmost face represents "the most severe nausea/vomiting imaginable" (10 points).[20,21]

Study Procedure

Randomization and Data Collection Process

Children who met the eligibility criteria and whose parents provided verbal consent were consecutively enrolled in the study. Children were allocated to the intervention and control groups in a 1:1 ratio using a computer-generated randomization scheme created through Randomization.com.[22] As each eligible participant was enrolled, the researcher assigned the participant to the corresponding group according to the predetermined randomization sequence. Before the foot bath procedure, the Child Information Form was completed for children in both the intervention and control groups through face-to-face interviews conducted by the researcher. Because of the nature of the intervention and the single-researcher study design, allocation concealment was not implemented.

Children in the intervention group received a 20-min foot bath, beginning 5 min before the initiation of chemotherapy following premedication and continuing during the first 15 min of chemotherapy. Children in the control group received no intervention. The BARF scale was administered to both groups before chemotherapy and again at the 15th min of chemotherapy. All randomized participants received the allocated intervention, completed the study, and were included in the final analysis. No participants were lost to follow-up or excluded from the analysis (Fig. 1).[23]

Foot Bath Intervention

Foot baths were administered in the patients' hospital rooms. Each child was positioned lying in bed, and

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Fig. 2. Foot bath device.[23]

their feet and ankles were placed into the warm water. The Beurer FB 35 Foot Bath and Massage Device was used for the intervention (Fig. 2).

During the foot bath, vibration and bubble massage were applied simultaneously to stimulate foot reflexology zones. The water temperature was set at 40°C using the device's built-in heating system, which maintained a constant temperature throughout the session. Each foot bath session lasted a total of 20 min, beginning 5 min before the initiation of chemotherapy and continuing during the first 15 min of chemotherapy.

The Beurer FB 35 device is an electric foot bath system suitable for use in children aged 8 years and older. It can heat water up to 40°C and maintain the temperature. The device provides foot reflex zone massage, vibrational massage, and bubble massage and includes a foot spa feature.

After each session, the device was cleaned using an appropriate disinfectant.

Foot Bath Temperature and Duration

A review of studies involving foot bath interventions showed that the water temperature ranged between 38–45°C and the duration of the bath varied between 10–30 min.[8–19] Based on this evidence, the water temperature in the present study was set at 40°C, and the foot bath intervention was standardized to a total duration of 20 min (5 min before chemotherapy and 15 min during chemotherapy).

Sample of the Study

Population and Sample

The population of the study consisted of children aged 8–18 years who were receiving chemotherapy and being followed between December 2022 and December 2023 in the pediatric hematology and oncology inpatient and outpatient clinics of the University Faculty of Medicine Children's Hospital.

Before starting the study, the required sample size for the intervention and control groups was determined using power analysis (G*Power software). The power analysis was performed using the BARF score means reported in the study by Yurdakul et al.[24] for the experimental group (1.43±1.45) and control group (4.80±2.07). The analysis indicated that 15 children per group, for a total of 30 participants, were required (comparison of two independent means; Type I error: 0.01, Type II error: 0.10, power: 0.90).

Inclusion and Exclusion Criteria

Inclusion Criteria

- Child and family voluntarily agreed to participate in the study,
- Child was between 8 and 18 years of age,
- Child had received chemotherapy at least once,
- Child had experienced chemotherapy-induced nausea and/or vomiting at least once,
- No impairment in skin integrity or sensory loss in the feet.

Exclusion Criteria

- Lack of voluntary participation by the child or family,
- Child had mental retardation, hearing impairment, or speech difficulties.

Statistical Analysis

Data were analyzed using the Statistical Package for the Social Sciences 24.0.

The BARF scores did not follow a normal distribution ($p>0.05$). Therefore, descriptive analyses and the Mann–Whitney U test were used. A significance level of $p<0.05$ was considered statistically significant.

Ethical Considerations

Written approval was obtained from the University Faculty of Medicine Children's Hospital and the Gaziantep University Clinical Research Ethics Committee (Date: November 24, 2022, and No: 2022/339). Before data collection, parents were informed about the study, and verbal consent was obtained from them. The research followed the ethical guidelines specified in the World Medical Association's Declaration of Helsinki.

RESULTS

It was found that 66.7% of the children in the intervention group were male and 46.7% were aged 8–10 years, whereas 60% of those in the control group were male and 66.7% were aged 8–10 years; additionally, 73.3% of the intervention group had leukemia, 46.7% had been diagnosed for 13 weeks or longer, 73.3% were in the consolidation phase, 46.7% were in week 13 or later of chemotherapy, 73.3% received Kytril and 26.7% received Avil as premedication, and 53.3% were treated with alkylating agents, whereas in the control group 66.7% had leukemia, 66.7% had been diagnosed for 13 weeks or longer, 73.3% were in the consolidation phase, 60.1% were in week 13 or later of chemotherapy, 80% received Kytril and 40% received Avil as premedication, and 26.7% received alkylating agents and antitumor antibiotics (Table 1).

When the mean BARF scores of the children in the intervention and control groups were compared, a statistically significant difference was found between the groups 5 min before the initiation of chemotherapy ($p<0.05$). However, there was no statistically significant difference between the intervention and control groups in the mean BARF scores at the 15th min of chemotherapy ($p>0.05$). Although the difference between the groups at the 15th min was not statistically significant, the intervention group had a lower mean BARF score compared to the control group. To account for the baseline difference in BARF scores, change scores (baseline BARF score minus the BARF score at the 15th min of chemotherapy) were calculated and compared between the groups. The intervention group demonstrated a significantly greater improvement in BARF scores than the control group (Mann–Whitney U=44.000, Z=-3.308, p=0.001) (Table 2).

Table 1 Distribution of sociodemographic and disease-related characteristics of children in the intervention and control groups

Sociodemographic and disease-related characteristics	Intervention group		Control group	
	n	%	n	%
Gender				
Female	5	33.3	6	40.0
Male	10	66.7	9	60.0
Age (years)				
8–10	7	46.7	10	66.7
11–14	5	33.3	3	20.0
15–18	3	20.0	2	13.3
Cancer type				
Leukemia	11	73.3	10	66.7
Lymphoma	3	20.0	1	6.7
Other	1	6.7	4	26.6
Time since diagnosis (weeks)				
1–6	4	26.7	1	6.7
7–12	4	26.7	4	26.7
≥13	7	46.7	10	66.7
Chemotherapy phase				
Induction	4	26.7	4	26.7
Consolidation	11	73.3	11	73.3
Chemotherapy week				
1–4	3	20	2	13.3
5–8	3	20	2	13.3
9–12	2	13.3	2	13.3
≥13	7	46.7	9	60.1
Premedication used				
Kytril (Granisetron hydrochloride)	11	73.3	12	80
Avil (Pheniramine hydrogen maleate)	4	26.7	6	40.0
Type of chemotherapy used				
Antimetabolites	3	20.0	3	20.0
Alkylating agents	5	53.3	4	26.7
Vinca alkaloids	2	13.3	2	13.3
Antitumor antibiotics	2	13.3	4	26.7
Enzymes	2	13.3	3	20.0
Platinum	0	0.0	2	13.3
Other (Etoposide)	1	6.7	2	13.3

DISCUSSION

A review of the literature revealed that no study has directly examined the effect of foot baths on CINV. Therefore, the findings of the present study were interpreted primarily in the context of research investigating the physiological and psychological effects of foot baths and massage. Studies evaluating the effect of foot massage on nausea and vomiting are also limited, and the available evidence is restricted to adult populations.[25]

Warm foot baths are widely used as a complementary and alternative therapy for managing various symptoms. Foot baths and foot massage have been applied across several health conditions. Previous research has shown that foot baths significantly increase salivary immunoglobulin A levels reduce cortisol levels, decrease sympathetic activity, and increase parasympathetic activity in both healthy and cancer patients – effects associated with analgesic and relaxing outcomes.[26,27] In healthy women, mechanically

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Table 2 Comparison of BARF scores before chemotherapy, at the 15th min of chemotherapy, and change in BARF scores between the intervention and control groups

Mean BARF scores in the intervention and control groups	Mean±SD	Min–max	Statistical analysis
Intervention group, 5 min before the initiation of chemotherapy	1.60±1.88	0–6	U=70.500; p=0.041*
Control group, 5 min before the initiation of chemotherapy	0.40±0.82	0–2	
Intervention group, 15th min of chemotherapy	0.53±1.18	0–4	U=95.500; p=0.392
Control group, 15th min of chemotherapy	1.33±2.69	0–10	
Intervention group, change in BARF score (baseline–15th min)	1.07±1.28	0–4	U=44.000; p=0.001*
	-0.93±2.12	-8–0	

*: p<0.05. BARF: Baxter retching faces scale; SD: Standard deviation.

stimulated warm foot baths have been shown to enhance parasympathetic activity, reduce sympathetic activity, and increase leukocyte and natural killer (NK) cell counts.[18] Other studies have demonstrated that foot baths improve blood flow and enhance parasympathetic nervous system activity.[17]

Among adults with chemotherapy-induced peripheral neuropathy, foot baths were found to be more effective than foot massage in increasing skin temperature, reducing neurotoxicity, and improving quality of life.[15] Foot massage has also been reported to reduce CINV in adult patients.[25] In addition, foot baths have been shown to rapidly improve pulmonary function in patients with bronchial asthma,[14] improve sleep quality in adults with insomnia,[9,10,12,13] relieve pain in diabetic peripheral neuropathy,[19] and improve quality of life related to chemotherapy-induced fatigue in cancer patients.[8] Studies in children have shown that foot baths reduce body temperature in febrile children,[11,16,28] and that foot massage reduces chemotherapy-related pain in pediatric cancer patients.[29] For these reasons, the use of foot baths in nursing practice has been recommended due to their physiological benefits.[18]

Based on these studies, foot baths have been reported to induce vasodilation, facilitate heat distribution, increase toxin oxidation, support thermoregulation by maintaining balance within the hypothalamic temperature-regulating center, and enhance blood circulation, thereby increasing the capacity of phagocytes to destroy microorganisms and detoxify the blood.[11] In addition, foot baths increase immunoglobulin A levels, reduce cortisol,[26,27] enhance parasympathetic activity while reducing sympathetic activation,[17,18,26,27] and elevate leukocyte and NK cell levels.[18] These physiological effects contribute to reducing pain, eliminating bacteria, relieving fatigue, promoting muscle relaxation, and supporting oxygen and nutrient delivery to the brain.[11] Massage has similarly been reported to reduce anxiety and pain, improve blood circulation, increase serotonin and dopamine levels, decrease cortisol, and suppress pain mechanisms.[30]

Despite the positive physiological mechanisms reported in the literature, no statistically significant difference was observed between the intervention and control groups in BARF scores at the 15th min of chemotherapy. However, when baseline differences were taken into account by comparing change scores, the intervention group demonstrated a significantly greater improvement in BARF scores than the control group. These findings suggest that although post-treatment scores alone did not differ significantly between groups, the intervention was associated with a greater reduction in nausea and vomiting over time.

These findings indicate that the intervention may contribute to reducing CINV, although the absence of a significant difference in post-treatment scores suggests that its effectiveness should be interpreted with caution. The significant improvement observed in the change-score analysis supports the potential benefit of the intervention; however, larger randomized controlled studies are needed to confirm these findings.

Limitations and Strengths

This study has several limitations. First, the small sample size may have prevented the clinically observed improvements from achieving statistical significance. In addition, a statistically significant difference in baseline BARF scores was observed between the intervention and control groups before chemotherapy, despite random allocation. This baseline imbalance may have influenced the post-intervention comparisons and should be considered when interpreting the findings. Furthermore, limiting the nausea and vomiting assessment to the 15th min of chemotherapy restricted the ability to evaluate the intervention's effects over a broader time frame.

The single-session design and intervention duration may also have limited the potential impact of warm foot baths and massage. Variations in cancer types and chemotherapy protocols among participants likely contributed to differences in nausea and vomiting responses, making homogeneous evaluation more difficult.

Furthermore, the effects of foot baths and massage may be influenced by psychological status, anxiety, and environmental stimuli – factors that are difficult to control and may have impacted the results. Since the intervention was evaluated only in the short term, its long-term effects could not be assessed.

Moreover, because nausea and vomiting were assessed only during the acute phase of chemotherapy, the findings are limited to the acute phase and should not be interpreted as reflecting the intervention's effects on delayed CINV. Future studies should evaluate both acute and delayed phases to provide a more comprehensive assessment of the intervention.

CONCLUSION

Although previous studies have shown that foot baths and massage exert positive physiological effects – such as increasing parasympathetic activity, reducing stress response, improving circulation, and promoting relaxation – the present study found no statistically significant difference between the intervention and control groups in post-treatment BARF scores. However, when changes from baseline were analyzed, the intervention group demonstrated significantly greater improvement in BARF scores than the control group. These findings suggest that warm foot bath and massage may contribute to reducing CINV; however, larger randomized controlled trials with more homogeneous patient populations, longer intervention periods, and multiple assessment time points are required before routine clinical implementation can be recommended.

Finally, the lack of previous studies examining the effects of foot baths and massage on CINV in pediatric populations limited the ability to compare findings with the existing literature. Because the few available studies were conducted only in adults, this further restricted the strength of the comparative analysis.

Although warm foot bath and massage showed a clinically favorable trend toward reducing nausea and vomiting, the current evidence is insufficient to recommend their routine use in clinical practice. These findings suggest that foot bath and massage may have potential as complementary supportive interventions; however, their effectiveness should be confirmed in larger randomized controlled trials with more homogeneous patient populations, longer intervention periods, and multiple assessment time points before clinical implementation can be recommended.

Ethics Committee Approval: The study was approved by the Gaziantep University Faculty of Medicine Children's Hospital and the Gaziantep University Clinical Research Ethics Committee (no: 2022/339, date: 24/11/2022).

Informed Consent: Before data collection, parents were informed about the study, and verbal consent was obtained from them.

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