



## Effect of Maternal Empowerment Training on Frequency of Gastrointestinal Complications in Children Undergoing Chemotherapy

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### Abstract

**Background:** Given the high prevalence of chemotherapy complications, it is essential to try limiting the side effects in order to prevent reduced quality of life in cancer patients, particularly children. The present study aimed to determine effect of maternal empowerment training on gastrointestinal complications in children undergoing chemotherapy.

**Methods:** This clinical trial study was performed on mothers with children under 12 years undergoing chemotherapy at the Bahrami Children's Hospital in Tehran (Iran) in 2017. Forty mothers were enrolled in the study via convenience sampling. The subjects were then randomly assigned to an intervention (n=20) and a control group (n=20). Data were collected using a checklist on gastrointestinal complications at baseline and two, four and eight weeks after the last training session. Statistical analysis of data was performed in SPSS 16.

**Results:** The frequency of gastrointestinal complications reduced significantly after the training in the intervention group ( $P<0.05$ ). There was no significant difference in the frequency of gastrointestinal complications before and after the intervention in the control group ( $P>0.05$ ). After the training, the frequency of gastrointestinal complications was significantly lower in the intervention group than in the control group.

**Conclusion:** The empowerment program could help improve mothers' knowledge about chemotherapy and associated complications, thereby reducing the frequency of such complications in children undergoing chemotherapy.

### ARTICLE HISTORY

Received: Aug 08 2020

Received in revised form: Dec 26 2020

Accepted: Jan 21 2021

Published online: Dec 21 2021

DOI: [10.29252/jgbrnm.18.2.41](https://doi.org/10.29252/jgbrnm.18.2.41)

### Keywords:

Mothers  
Empowerment  
Neoplasm  
Gastrointestinal complications  
Child

Article Type: Original Article



### Highlights:

#### What is current knowledge?

Knowledge about pediatric cancer treatments, including chemotherapy, is high, but little is known about parent education methods to reduce the effects of chemotherapy.

#### What is new here?

Different methods are used to educate the parents of sick children. The empowerment model helps mothers to become more aware of the disease and its complications and to have more skills in managing the disease and its complications.

### Introduction

Cancer is the second leading cause of death after cardiovascular disease in the United States (1). Childhood cancers are rare and account for only 1% of new cancer cases (2) but may be life threatening (3). There are various types of cancer in children that are different from those seen in adults. For instance, lymphoma, leukemia and brain tumors can be seen in more than half of children with cancer but account for less than 10% of cancer cases in adults (4). Childhood cancer is the second leading cause of death in children under 14 years of age in Iran (5). Fortunately, the advancement of science has increased the survival of cancer patients, and many treatment strategies have been discovered to cure these patients. Chemotherapy is commonly used for treatment of cancer, particularly childhood cancers. It refers to the use of drugs in order to eliminate cancer cells or slow down their growth. Chemotherapy aims to reduce or eliminate symptoms of cancers and is used alone or along with other treatments such as surgery or radiation therapy (6-8). Chemotherapy is more applicable in children than in adults because of the higher efficacy. In addition, children can better tolerate the side effects of chemotherapy compared to adults. Radiotherapy is less commonly

used in children because of the long-term side effects. Treatment of childhood cancer is often through outpatient chemotherapy approach using programmable infusion pumps, oral chemotherapy regimen and early discharge from hospital with outside-home care and treatment monitoring (9). Antineoplastic drugs target cell cycle and therefore affect both healthy and cancer cells (10, 11). Given the high prevalence of chemotherapy complications in adults and children, it is essential to try limiting the side effects in order to prevent reduced quality of life in cancer patients, particularly children (12). In a study on chemotherapy complications in adolescents, 59% of adolescents reported that complications of anti-cancer therapies were worse than the cancer itself (13). Other studies on patients undergoing chemotherapy indicated some degrees of oral mucositis that lasted about 7 to 14 days (14, 15). In another study, the most common side effects of chemotherapy-related gastrointestinal complications included nausea, vomiting, aphthous stomatitis, diarrhea and odynophagia in children undergoing chemotherapy (13).

Children are dependent on their families for receiving care; hence, the presence of an active family member in child care is highly effective in the treatment outcome. In most families, mothers play the primary role in child care (16). In the past two decades, treatment of various diseases has shifted from hospitals to homes. More than 90% of cancer care and treatment are also carried out in an outpatient manner and at home. Teaching the patients, their family members and caregivers as well as active participation in providing care facilitate the care transfer from hospital to home (17). Therefore, empowerment is an important approach to engage and educate patients and caregivers (18). Empowerment, as a collaborative learning approach, requires close attention to the family and its needs as the center of care. Helping individuals and families to acquire an active role in health care is more important than aiding empowerment (17, 19). The Iranian empowerment model is derived from a research-based grounded theory based on Bandura's theory to improve chronic diseases. The model aims at empowering families to improve health and involves threat perception, problem-solving, educational participation and evaluation (20). This model also

strengthens independence and respects the patient and family's choices, values, beliefs and cultural backgrounds (21). Given the importance of this model and the insufficient research on its impact on children with cancer, the present study aimed to examine effect of maternal empowerment training on frequency of gastrointestinal complications in children undergoing chemotherapy.

## Methods

This clinical trial study was conducted in 2017 with a pretest-posttest design. The statistical population included 50 mothers of children with cancer undergoing chemotherapy at the Bahrami Children's Hospital in Tehran, Iran. The samples size was calculated based on the results of a pilot study and according to the sample size formula with a 95% confidence level and 90% test power. The minimum sample size was estimated to be 15 per group that was increased to 20 according to 30% drop out. Inclusion criterion was having a child less than 12 years of age with a definite diagnosis of cancer receiving chemotherapy (at least one or maximum two courses). Exclusion criteria included having debilitating diseases, receiving special training courses such as chemotherapy training, working as healthcare personnel, unwillingness to continue cooperation and child's death. Overall, 40 eligible mothers were enrolled using the convenience sampling method. The subjects were then randomly assigned to an intervention (n=20) and a control (n=20) group (Fig. 1).

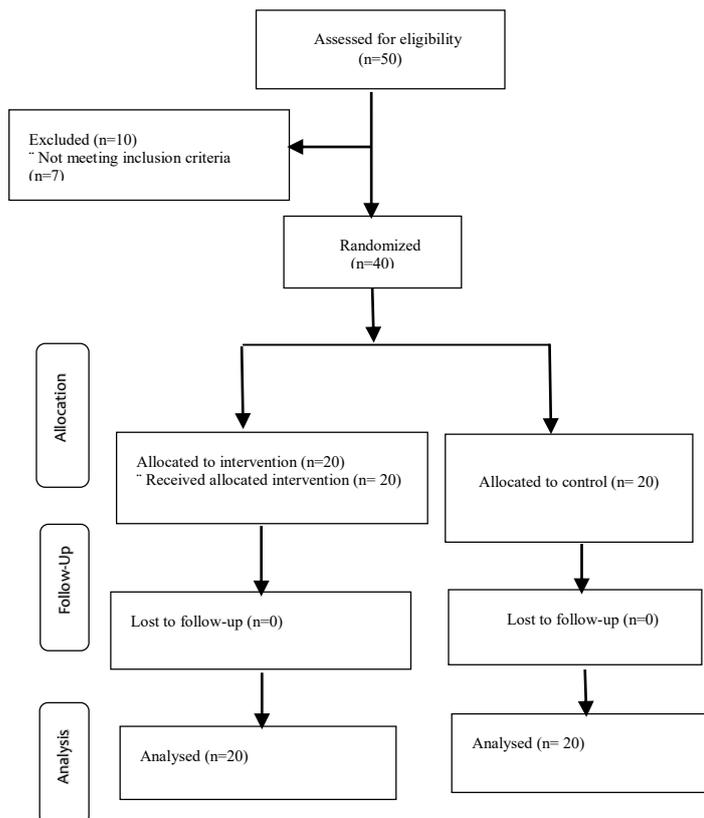


Figure 1. The consort diagram of the research

The study received approval from the ethics committee of Islamic Azad University, Tehran Medical Sciences Branch (ethics code: IR.IAU.TMU.REC.1396.64). Written informed consent was taken from all participants after detailed explanation of the study objectives. Data collection tools included a demographic information (age, sex, marital status, education level, etc.) questionnaire and a checklist of symptoms of acute and common gastrointestinal complications of chemotherapy in children. The demographic information questionnaire was completed by the researcher. The checklist included 14 questions on symptoms of gastrointestinal complications that were selected according to oncology and pediatric textbooks (1, 9, 22- 24) and the side effect checklist of the American Cancer Society (25). The content validity index and content validity ratio were used to confirm the content validity of the checklist. The following criteria were used in order to calculate the content validity index; simplicity, clarity and relevancy. Based on the results, all items were accepted with a content validity index of greater than 83%. The checklist's reliability was also approved by obtaining a Cronbach's alpha coefficient of 0.88. The empowerment training was only held for the intervention group and the control group received no training. The training consisted of five one-hour sessions held in groups of five individuals (Table 1). The researcher completed the checklist for both groups at baseline and two, four and eight weeks after the last training session. At the end of the study, all issues relating to empowerment and training sessions were given to the control group in forms of CDs and

booklet. Data were analyzed in SPSS Statistics for Windows, version 16 (SPSS Inc., Chicago, Ill., USA). Data were presented in mean and standard deviation, and for comparison between before and after, the Cochran test were used. Also for comparing mothers empowerment score, in intervention and control groups, Mann-Whitney U test were used. All statistical analyses were carried out at significance level of 0.05.

Table 1. The four steps of empowerment model used for mothers of children with cancer

Step	Topic	Objectives
First	Understanding the threats	The first step in the empowerment model is to increase threat perception in the mothers to resolve their lack of awareness and knowledge in this regard.
Second	Troubleshooting	At this stage, mothers were practically faced with problems and were informed of each other's experiences in solving chemotherapy-associated problems.
Third	Educational participation	At the end of each session, to promote self-confidence and self-esteem, mothers were asked to share the information discussed in the sessions by exchanging information through educational participation. Mothers were also asked to explain the information to other family members.
Fourth	Assessment	At this stage, before each session, questions and answers were asked about the topics discussed to ensure learning the contents of the previous sessions.

## Results

The mean age of children and mothers was  $4.75 \pm 2.25$  and  $31.33 \pm 4.40$  years, respectively. All children had health insurance. The frequency of girls in the intervention and the control groups was 75% and 35%, respectively. Most of the subjects in the intervention group (70%) and the control group (90%) were not students. All mothers were married. In addition, 55% of mothers in the intervention group had high school diploma and 45% of mothers in the control group had secondary education. Moreover, 85% of subjects in the intervention group and 90% of subjects in the control group were mothers' assistants in child care.

As shown in table 2, there was no significant difference between the two groups in terms of the frequency of gastrointestinal complications before the intervention. However, the frequency of gastrointestinal complications was lower in the intervention group than in the control group two, four and eight weeks after the empowerment training.

The results of the chi-square test indicated no significant difference between the two groups in terms of gastrointestinal complications before the intervention, but the Cochran's test results confirmed a significant reduction in the frequency of gastrointestinal complications in the intervention group after the empowerment training ( $P < 0.05$ ). The results of the McNemar test in binary comparisons indicated that the frequency of the complications decreased significantly two weeks after the intervention compared to baseline ( $P = 0.033$ ). This significant decrease was observed in the following evaluations ( $P = 0.037$  in the fourth week and  $P = 0.038$  in the eighth week). The chi-square test results also indicated that gastrointestinal complications were significantly lower in the intervention group than in the control group in all posttest ( $P < 0.05$ ) (Table 3).

In the control group, the frequency of gastrointestinal complications was highest (75%) in the pretest and lowest (60%) four weeks after chemotherapy ( $P > 0.05$ ). Results of the chi-square test indicated that the frequency of gastrointestinal complications was significantly lower in the intervention group than in the control group in all posttest stages ( $P < 0.05$ ) (Table 4).

## Discussion

According to the results, teaching mothers decreased the incidence and severity of gastrointestinal complications of chemotherapy in children with cancer. This is consistent with the results of a study by Asgarabad et al. (26). Similarly, Karimi et al. (2017) also showed that an educational program could significantly reduce the frequency of nausea and vomiting in cancer patients undergoing chemotherapy. They concluded that the training program could be considered a complementary approach for anti-inflammatory drugs (27).

In a study by Partovi et al. (2013), the prevalence of gastrointestinal complications was high in children with leukemia undergoing chemotherapy (13). In another study by Sizen et al. (2012), the prevalence of gastrointestinal complications and acute constipation in cancer children undergoing chemotherapy was high (24). In a study by Cheng (2008), self-care and quality of life increased and the frequency of chemotherapy side effects decreased after a training program and telephone follow-up for four weeks (25). In line with our findings, Karimi et al. (2014) reported that a training program could significantly reduce chemotherapy-related gastrointestinal complications in patients (26). The implementation of empowerment models is more effective than regular trainings in reducing the frequency of chemotherapy-associated side effects. In other words, modern methods of training along with commonly used methods, such as learning through booklets, telephone follow-up and continuous training could

improve mothers and patients' knowledge about chronic diseases. In this regard, Davarpanah et al. demonstrated that the empowerment model was effective in improving the patient training (27).

We did not consider allergy to medications, patients' immunity level and diet during the study period, which is a limitation of this study. Therefore, it is recommended to consider these possible confounding factors in future studies.

## Conclusion

The empowerment training increased knowledge and understanding of the mothers about symptoms and reduced the frequency of gastrointestinal complications following chemotherapy. Therefore, implementation of such training programs could help increase quality of life and the treatment outcome in children undergoing chemotherapy.

## Acknowledgements

We will like to extend our gratitude to all participants for their cooperation in this research.

## Funding source

There are no conflicts of interest to declare.

## Ethical statement

The present manuscript was derived from a master's thesis approved by the Islamic Azad University, Tehran Medical Sciences, Iran. This clinical trial was also registered on the Iranian Registry of Clinical Trials (IRCT20180121038467N1). We are grateful to the staff of the Islamic Azad University of Tehran and Bahrami Children's Hospital as well as patients and their families for their cooperation.

## Conflict of interest

The authors declare that there is no conflict of interest

## Author contributions

All authors have contributed significantly to this study and the preparation of this manuscript and we agreed with its contents. The specific contributions include: Leila Lashgari, Shamsolmoluk Jalal Manesh in writing the background, reviewing the literature, and discussing the findings, while Leila Lashgari, Mohammad Kazem Naeini did the data collection and analysis

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**Table 2. Relative frequency distribution of gastrointestinal complications in the study groups before the intervention and two, four and eight weeks after the intervention**

Gastrointestinal complications	Intervention group				Control group			
	Before the intervention	After two weeks	After three weeks	After eight weeks	Before the intervention	After two weeks	After three weeks	After eight weeks
<b>Anorexia</b>	22.3(16)	12.6(14)	12.1(17)	10.5(17)	25.2(17)	23.9(17)	19.1(16)	20.3(16)
<b>Nausea</b>	17.2(12)	13.3(15)	8.2(12)	6.7(11)	14.5(10)	13.6(10)	12.2(10)	13.2(10)
<b>Vomiting</b>	15.3(11)	9.4(10)	7.2(10)	5.3(9)	18.3(12)	18(13)	17.2(14)	16.2(12)
<b>Diarrhea</b>	8.5(6)	6.8(8)	5.1(7)	4.6(8)	11.3(7)	9.8(7)	8.2(7)	10.1(8)
<b>Constipation</b>	6.7(5)	2.9(3)	2.4(4)	2.9(5)	5.7(4)	4.7(3)	3.2(3)	5.2(4)

**Table 3. The frequency distribution of gastrointestinal complications in the intervention and control groups before and after the intervention**

Gastrointestinal complications	Intervention group		Control group	
	Mean±SD	Cochran's test result	Mean±SD	Cochran's test result
<b>Before the intervention</b>	2.10±0.66		2.20±0.63	
<b>Two weeks after the intervention</b>	1.50±0.32	P-value=0.011	2.10±0.27	P-value=0.328
<b>Four weeks after the intervention</b>	1.32±0.34		1.80±0.46	
<b>Eight weeks after the intervention</b>	1.23±0.26		1.95±0.47	

**Table 4. Comparison of absolute and relative frequency distribution of gastrointestinal complications in the intervention and control groups in the posttest stages**

Gastrointestinal complication	Mean ± SD	Mean ± SD	Mann-Whitney U test
<b>Two weeks after the intervention</b>	1.50±0.32	2.10±0.27	P<0.001
<b>Four weeks after the intervention</b>	1.32±0.34	1.80±0.46	P<0.001
<b>Eight weeks after the intervention</b>	1.23±0.26	1.95±0.47	P<0.001

SD: standard deviation

**How to Cite:**

Leila Lashgari, Shamsolmoluk Jalal Manesh, Mohammad Kazem Naeni. Effect of Maternal Empowerment Training on Frequency of Gastrointestinal Complications in Children Undergoing Chemotherapy. *Journal of Research Development in Nursing & Midwifery*, 2021; 18 (2): 41-44



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