



# EFFECT OF NUTRITION COUNSELING ON GASTROINTESTINAL COMPLICATIONS IN PATIENTS UNDERGOING RADIATION FOR ABDOMINAL AND PELVIC CANCER: A RANDOMIZED CLINICAL TRIAL

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**Abstract – Objective:** Nowadays, the rate of referral to radiotherapy clinics has also increased due to the development of medical facilities and increased diagnosis of malignant diseases. Implementation of counseling programs by the nurses and health care providers for improving nutritional patterns and simultaneously prevention in cancer patients may improve their health level. Therefore, this study was designed to determine the effect of dietary counseling on gastrointestinal complications in patients receiving abdominal and pelvic radiotherapy.

**Patients and Methods:** In this randomized clinical trial study, 80 patients referred to the radiotherapy ward of Tohid Hospital in Sanandaj (Kurdistan Province, Iran), during 2018-2019 were randomly categorized into two 40-subject intervention and comparison groups. They received nutritional counseling three times a week in one-hour sessions over 2 consecutive weeks. After that, in the 4th week, both groups were assessed for gastrointestinal complications using the Gastrointestinal Symptom Rating Scale.

**Results:** The patients in the intervention group had a mean age of  $59.95 \pm 1.25$  years old, and those in the comparison group had a mean age of  $61.87 \pm 1.41$  years old. Moreover, the mean score of gastrointestinal complications was equal to  $5.55 \pm 0.81$  in the comparison group, and it was similar to  $1.49 \pm 0.25$  in the intervention group, which was significantly lower in the intervention group than the control group ( $p$ -value = 0.0001). The mean score of the scale in all dimensions except the constipation dimension was not significantly different between the two study groups, and it was significantly lower in the intervention group than that of the control group ( $p$ -value = 0.0001).

**Conclusions:** The findings of the present study revealed that nutrition counseling could be useful in controlling and decreasing acute gastrointestinal complications caused by abdominal and pelvic radiotherapy.

**KEYWORDS:** Nutrition Counseling, Gastrointestinal Complications, Abdominal and pelvic cancer, Radiotherapy.

## INTRODUCTION

Cancer is a destructive and chronic multifactorial disease affecting all aspects of an individual's quality of life<sup>1</sup>. According to the latest statistics of the World Health Organization (WHO), Geneva, Switzerland in 2018, 1.7 million new cases and 609.640 deaths of cancer occur in the United States each year, and the can-

cer-related death rate is expected to reach 11.4 million annually by 2030, among which 0.70% of cases occur in underdeveloped countries<sup>2</sup>. In Iran, 70.000 new cases of different types of cancer have been identified that will continue to grow in the future years<sup>3</sup> and it is the third leading cause of death in Iran after cardiovascular disease and accidents<sup>4</sup>. Nowadays, radiotherapy is one of the main methods of controlling malignancies<sup>5</sup>.



Radiotherapy (RT) is defined as the technique of using high-energy beams, usually x-rays or similar beams like electrons or protons to kill cancer cells<sup>6</sup> that act by damaging the DNA of cancer cells<sup>7</sup>. About one million people require pelvic RT annually<sup>8</sup>. It was estimated that 0.50% of patients with malignancy would receive some forms of RT during their treatment<sup>9</sup>. The success of RT depends on careful monitoring and control of the patients during treatment and accurate determination of the target tissue with complete resolution. Besides the therapeutic effects of this method, some patients will experience complications due to radiation damage to healthy tissues<sup>10</sup>. Gastrointestinal complications are prevalent in the patients receiving RT<sup>11</sup>. RT causes changes in bacterial flora, vascular permeability of mucosal cells, and intestinal irritation. The damage depends on the amount of radiation, radiation field, and treatment duration<sup>12</sup>. Acute complications start in the second week of RT and last for 4 to 5 weeks. These complications include diarrhea, abdominal pain, nausea, impaired nutrient absorption, heartburn, and rectal bleeding<sup>13</sup>. If left uncontrolled, these complications contribute to the chronic effects such as excessive rectal bleeding, bowel obstruction, weight loss, and secondary cancers that will all influence an individual's quality of life. Despite treatment for primary disease, chronic complications lead to debilitating and sometimes fatal results to the patient<sup>14</sup>. Various measures have been proposed to decrease gastrointestinal complications caused by RT, including advanced RT, positioning of the patient during RT, as well as pharmacological and non-pharmacological interventions, among which dietary modification is significant<sup>5</sup>. In this regard, nutrition counseling as the first recommended intervention for the patients is a professional communication process aimed at enhancing patients understanding of nutritional issues that may lead to long-term changes in dietary habits<sup>15</sup>. Dietary modification can reduce gastrointestinal complications. Interventions recommended for prevention and delaying progression of gastrointestinal complications after RT consist of the modification of fat, lactose, and dietary fiber intake<sup>16</sup>.

Moreover, receiving restricted diets is not a priority regarding nutritional interventions in these patients<sup>17</sup>. Nurses are among the most important members of treatment team playing a significant role in protecting life and health of the patients<sup>18</sup>. Counseling is one of key roles of the healthcare team including nurses; however, it has been less addressed so far<sup>19</sup>. Access to education for the public is said to be the quickest and most effective way of achieving social justice. Education, as an independent task is a major part of counseling, and it is a main responsibility of health care workers including nurses<sup>20</sup>. Since, the nurses have more access to the patients; they can spend more time on counseling, leading to complete counseling<sup>21</sup>. Today, rate of referral to RT clinics has also increased due to development

of medical facilities and increased diagnosis of malignant diseases. Implementation of counseling programs by the nurses and health care providers for improving nutritional patterns and simultaneously prevention or stopping gastrointestinal problems in cancer patients may enhance their health level. In fact, effectiveness of treatment may be doubled and additional direct and indirect costs imposed on the health care system may be prevented through provision of training in different counseling sessions. Accordingly, the present study was conducted to discuss the effect of nutrition counseling in the form of individual and clinical counseling on gastrointestinal complications in patients undergoing abdominal and pelvic RT, hoping that the results of this study could be useful to improve the future planning for the nutrition of these patients.

## PATIENTS AND METHODS

This prospective randomized clinical trial study performed on 80 patients referred to Tohid Hospital in Sanandaj, Kurdistan Province, Iran, during 2018-2019. Patients aged between 18 to 84 years old pathologically diagnosed with abdominal and pelvic cancer (stomach, intestine, prostate, bladder, testis, and sarcoma) and recipients of abdominal and pelvic RT who were admitted to the hospital for the first week of radiation were included in the study. Drug users and the patients experiencing critical conditions during RT were excluded from the study.

After investigation of these inclusion and exclusion criteria, the patients were randomly categorized into intervention and comparison groups. Randomization was performed by block randomization method using randomization software. The sample size was calculated as 40 subjects in each group, considering the power of 80% and a confidence level of 95%. This study was designed as a double-blind study to prevent information bias so that the subjects of the research and the methodologist were not aware of group assignment.

The nutritional training package was considered an intervention. This package was prepared using the opinions of the experts, including clinical scholars and nutritionists. The patients in the intervention group received nutritional training by the researcher individually and through face-to-face counseling in the morning shift at the RT Department of Tohid Hospital (Sanandaj, Kurdistan Province, Iran) in one-hour sessions three times a week over 2 consecutive weeks. In the first session, the researcher became familiar with the patients, and their dietary habits and nutrition, which is called nutrition science, were investigated. Then, necessary training was provided based on the patients' need to improve their awareness of the disease, its treatments, and complications (especially RT). Besides

desired training, training pamphlets containing useful dietary recommendations to prevent gastrointestinal side effects were developed and formulated for more effectiveness of the intervention based on the opinions of clinical experts and nutritionists that were given to the intervention group after the training package.

Primary outcomes in this study were gastrointestinal complications that were measured using the Gastrointestinal Symptom Rating Scale (GSRS). The GSRS consists of 15 items assessing five dimensions of gastrointestinal complications (abdominal pain, reflux, diarrhea, indigestion, and constipation), and it is ranked based on a 7-point Likert scale ranging from strongly satisfied to strongly dissatisfied, in which higher score indicates more severe symptoms. The validity and reliability of this questionnaire were confirmed in the study by Kulich et al<sup>22</sup>, with a reliability coefficient of 0.61 to 0.95. Additionally, the reliability of the questionnaire used in this study was assessed using Cronbach's alpha method, which ranged from 0.74 to 0.89 for all the dimensions.

**Ethical Considerations**

The study was approved by the Local Ethics Committee of Kurdistan University of Medical Sciences (Ethics Code of 20180610040031) and was registered in the Iranian Registry of Clinical Trials (IRCT.ir) (ID No.: IRCT20180610040031N1). In this study, informed consent was obtained from all the subjects who participated in the research and their partners.

**Statistical Analysis**

The descriptive statistics presented as mean and Standard Error of the mean (SE). Repeated two - way ANOVA was used to simultaneously analyze the average difference of the dependent variables between the two study groups and between the tests. If the main effect of the group, the main impact of the test, or the interaction between the groups and the tests were significant, the difference between the two tests within each group was verified using one-way ANOVA. The Least Significant Difference (LSD) was calculated for post verification, and the Paired Samples *t*-test confirmed the difference between the two tests within the same group. A *p*-value of less than 0.05 was considered statistically significant.

**RESULTS**

In this study, 120 people were included in the statistical population, among which 40 people were excluded from the study due to not meeting the inclusion criteria and lack of complete consent to participate in the study, and randomization was eventually performed on 80 patients who were divided into two 40-subject groups of intervention and control (comparison). During the research and implementing the intervention, 2 patients were excluded from the intervention group due to the lack of positive results. In the end, 38 patients in the intervention group and 40 patients in the control group were analyzed (Figure 1).

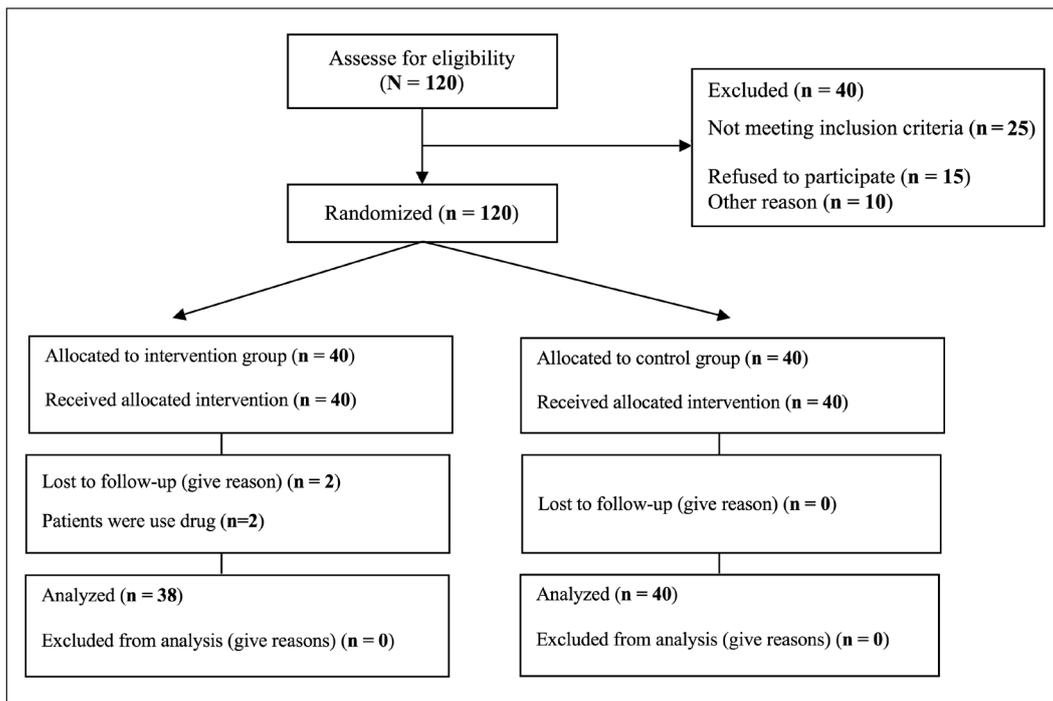


Fig. 1. The diagram CONSORT of study design.



**TABLE 1.** Baseline variables of intervention and comparisons groups.

	<b>Intervention Group (n=38)</b>	<b>Comparison Group (n=40)</b>	<b>p-value</b>
Age	59.95 ± 1.253	61.87 ± 1.411	0.154 <sup>a</sup>
Weight	61.50 ± 0.718	59.30 ± 0.716	0.893 <sup>a</sup>
Height	168.17 ± 0.879	167.62 ± 0.782	0.672 <sup>a</sup>
BMI	21.83 ± 0.297	21.15 ± 0.270	0.463 <sup>a</sup>
<b>Cancer Type</b>			
Rectum	2 (5 %)	4 (10 %)	0.217 <sup>b</sup>
Cervix	4 (10 %)	6 (15 %)	
Endometrium	3 (7.50 %)	3 (7.50 %)	
Prostate	16 (40 %)	16 (40 %)	
Testis	2 (5 %)	2 (5 %)	
Sarcoma	3 (7.50 %)	3 (7.50 %)	
Stomach	10 (25 %)	10 (25 %)	
<b>History of Radiotherapy</b>			
Yes	13 (32.50 %)	16 (40 %)	0.485 <sup>b</sup>
No	27 (67.50 %)	24 (60 %)	
<b>History of Chemotherapy</b>			
Yes	27 (67.50 %)	25 (62.50 %)	0.639 <sup>b</sup>
No	13 (32.50 %)	15 (37.50 %)	

<sup>a</sup>t-test; <sup>b</sup>Chi-square test

The results indicated no statistically significant difference in demographic and contextual characteristics between the intervention and control groups (Table 1).

The main effect of the test on abdominal pain, reflux, diarrhea, indigestion, and constipation was significant (Table 2). Before the intervention, gastrointestinal symptoms were evaluated in both study groups.

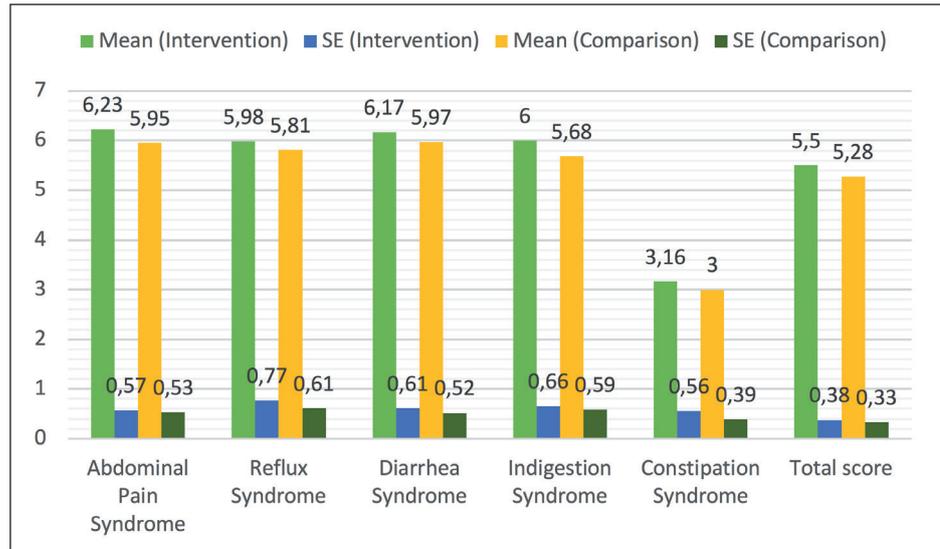
There was no significant difference between the two study groups in this regard, indicating that gastrointestinal symptoms were the same in both groups before the intervention except for indigestion syndrome and total score of gastrointestinal symptoms scale (*p*-value = 0.001) (Table 2 and Figure 2). However, after the intervention, comparison of gastrointestinal symptoms between the two study groups showed a statistically sig-

**TABLE 2.** Changes in primary outcomes after interventions.

<b>Domains</b>	<b>Group</b>	<b>Baseline</b>	<b>MD p-value (95% CI)</b>	<b>After intervention</b>	<b>MD p-value (95% CI)</b>	<b>p-value</b>
Abdominal Pain Syndrome	IG (n=38)	6.23 ± 0.571	-0.26 ± 0.127	1.49 ± 0.360	4.51 ± 0.240	Group 0.452
	CG (n=40)	5.95 ± 0.530	0.038	6.00 ± 1.39	0.0001	Test 0.001
			-0.52, -0.01		4.03, 4.99	Group & test 0.121
Reflux Syndrome	IG (n=38)	5.98 ± 0.771	-0.17±0.162	1.58 ± 0.43	4.36 ± 0.257	Group 0.826
	CG (n=40)	5.81 ± 0.610	0.296	5.49 ± 1.48	0.0001	Test 0.000
			-0.49, 0.15		3.84, 4.87	Group & test 0.388
Diarrhea Syndrome	IG (n=38)	6.17 ± 0.611	-0.19±0.130	1.59 ± 0.42	4.60 ± 0.203	Group 0.490
	CG (n=40)	5.97 ± 0.523	0.139	6.20 ± 1.12	0.0001	Test 0.010
			-0.46, 0.06		4.20, 5.01	Group & test 0.298
Indigestion Syndrome	IG (n=38)	6.00 ± 0.662	-0.31±0.141	1.53 ± 0.47	4.32 ± 0.23	Group 0.830
	CG (n=40)	5.68 ± 0.592	0.039	5.85 ± 1.27	0.0001	Test 0.000
			-0.60, -0.01		3.86, 4.78	Group & test 0.365
Constipation Syndrome	IG (n=38)	3.16 ± 0.566	-0.16±0.114	1.28 ± 0.285	1.72 ± 0.125	Group 0.361
	CG (n=40)	3.00 ± 0.390	0.150	3.01 ± 0.674	0.0001	Test 0.000
			-0.39, 0.06		1.47, 1.97	Group & test 0.118
Total score	IG (n=38)	5.50 ± 0.389	-0.21±0.087	1.49 ± 0.253	4.06 ± 0.158	Group 0.981
	CG (n=40)	5.28 ± 0.335	0.015	5.55 ± 0.841	0.0001	Test 0.001
			-0.39, -0.04		3.74, 4.37	Group & test 0.540

IG: Intervention Group, CG: Control Group, MD: Mean Difference.

**Fig. 2.** The mean and SE of primary outcome in two groups of study before intervention.



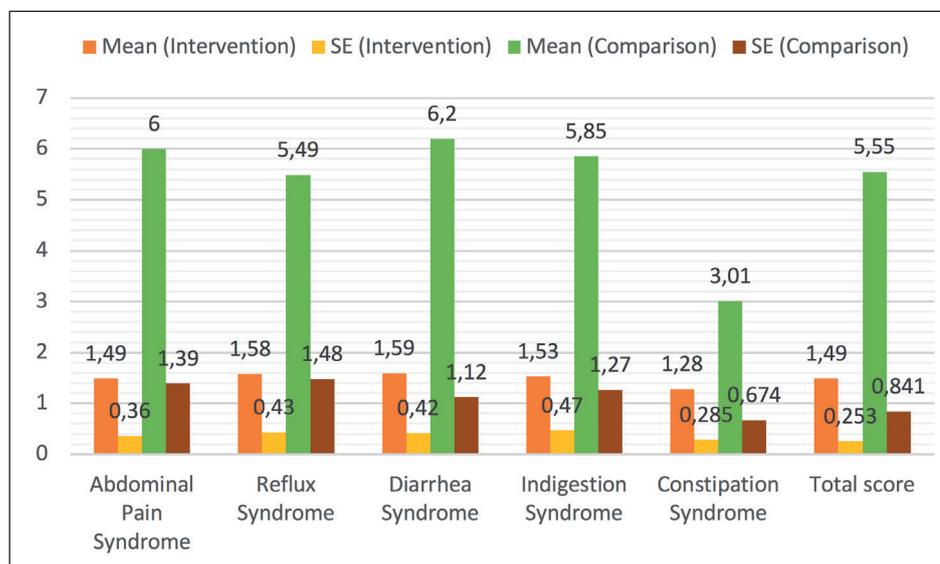
nificant difference ( $p$ -value = 0.0001) (Table 2 and Figure 3). Furthermore, the effect of scores of gastrointestinal symptoms before the intervention and mean score of gastrointestinal symptoms after the intervention were compared in two groups using ANOVA with control, which were statistically significant. Generally, the main effect of the test on abdominal pain, reflux, diarrhea, indigestion, and constipation was significant (Table 2).

**DISCUSSION**

Gastrointestinal complications are prevalent in patients undergoing RT<sup>12</sup>. It is estimated that approximately one million people require pelvic RT annually<sup>8</sup>. According to previous studies, it was determined that in 0.25% of patients undergoing RT, the gastrointestinal complications would sponta-

neously recover after the end of their course, while severe symptoms of gastrointestinal disorders will remain in 5 - 10% of the patients even after the end of RT<sup>22</sup>. The results of the present study are in line with those of previous studies. Woodlock et al<sup>23</sup> addressed the effect of fiber-containing diet on gastrointestinal complications in patients with gynecological cancer undergoing RT, and they demonstrated that fiber-containing diet recommendations were effective in reducing gastrointestinal complications in the patients. Finally, they concluded that the consumption of low fiber foods should be avoided, and they suggested further studies in this context. Wedlake et al<sup>24</sup> and Linn et al<sup>25</sup> investigated the effect of probiotics on diarrhea and abdominal pain, and they showed the useful role of probiotics in reducing complications. Soto-Lugo et al<sup>26</sup> compared low oligosaccharide and monosaccharide-containing diets

**Fig. 3.** The mean and SE of primary outcome in two groups of study after intervention.





and the Mexican diet in the patients and suggested that diets containing oligosaccharide and monosaccharide were less effective in reducing acute gastrointestinal complications. On the other hand, Miller et al<sup>27</sup> studied the effect of sulfasalazine on gastrointestinal complications in the patients undergoing pelvic RT and found that it was not valid on gastrointestinal complications, and these complications increased following administration of sulfasalazine. The present study may differ from studies mentioned above in terms of the number of studied subjects, the types of studied cancers, and, most importantly, the kind of intervention<sup>27</sup>.

Since, so far, there is no study investigating the effect of nutrition counseling on gastrointestinal complications in various types of cancers involving the abdominal and pelvic organs, this study may not be compared with other studies. One of the most critical cases to be studied on the gastrointestinal complications in patients receiving abdominal and pelvic RT as shown in this study is the clinical counseling in consecutive sessions during treatment based on dietary needs of the patients and according to dietary habits of each person that can be effective in reducing the incidence of gastrointestinal complications.

## CONCLUSIONS

This study was carried out to evaluate the effect of nutritional counseling on gastrointestinal complications in cancer patients undergoing abdominal and pelvic RT. The results of the study showed that the post “t” mean of gastrointestinal complications was lower in the intervention group than that of the comparison group, and this difference was statistically significant. The mean total score of gastrointestinal complications was statistically significant in the five studied dimensions in the comparison group before and after the intervention. Preventive and therapeutic measures to prevent or decline gastrointestinal complications in these patients may be useful depending on their particular circumstances. Results of the present study showed that nutrition counseling is valid on gastrointestinal complications in patients undergoing RT for abdominal and pelvic cancer.

## CONTRIBUTIONS:

All the authors contributed to the design of the research. RKH, ZS, and MMK collected the data. MY and DR conducted the analyses and interpreted the data. Also, all the authors contributed to preparing the first draft of the manuscript. MY, DR, and RKH edited the first draft. All the authors reviewed commented and approved the final draft.

## ACKNOWLEDGEMENT:

The authors would like to thank the research assistant of Kurdistan University of Medical Sciences and the patients who collaborated with us in the conduction of this study.

## CONFLICT OF INTEREST:

There are no conflicts of interest.

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