The Effects of Individual Diet Therapy on Food Intake, Quality of Life, and Related Serum Proteins in Patients with Breast Cancer: A Randomized Clinical Trial

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ABSTRACT

Background: In cancer patients, weight loss due to malnutrition has a significant impact on the patients’ treatment and quality of life. This study aimed to determine the appropriate therapeutic strategy to control the side effects of chemotherapy in patients with breast cancer to improve their health, quality of life, and nutritional status.

Methods: In our prospective study, we examined gastric cancer patients who were Seventy patients undergoing chemotherapy were included and randomly divided into intervention (n=35) and control groups (n=35). The intervention group received an individualized diet according to their nutritional needs for eight weeks, and the control group received dietary advice on the side effects of chemotherapy. Malnutrition, nutritional barriers, and patients’ quality of life were evaluated by PG-SGA, nutritional barriers, and QLQ-C30 questionnaires. Serum proteins were also assessed at the beginning and the end of the study.

Results: The patients’ mean age was 50.91±1.72 years in the intervention group and 51±1.35 in the control group. According to the PG-SGA questionnaire classification, 68.5% of patients had malnutrition at baseline. In the intervention group, the mean score of PG-SGA decreased, which indicated an improvement in patients’ nutritional status. Increased scores in the functional section of QLQC30 and a decrease in the symptom section of this questionnaire indicated the improved quality of life in patients undergoing treatment at the end of the intervention. Albumin (P<0.001) and hemoglobin (P<0.001) levels increased in the intervention group, while there were no significant changes in these variables of the control group. Serum levels of ferritin did not show significant changes in either the intervention or the control group.

Conclusion: Identifying nutritional barriers in breast cancer patients and individual diet therapy based on these barriers and nutritional needs reduces nutritional barriers. Consequently, malnutrition would decline, and the quality of life may enhance in these patients.

Keywords: Breast Cancer, Diet Therapy, Malnutrition, Chemotherapy, Randomized Clinical Trial
INTRODUCTION:

Cancer is one of the leading causes of death worldwide. As a non-communicable disease, it is the second leading cause of death after cardiovascular disease (CVD) in developed countries (1). Breast cancer is responsible for 33% of all cancers in women and 20% of deaths from cancer. The incidence of breast cancer increases with age, although it decreases slightly after menopause (2). The low incidence of breast cancer in Asian women is attributed to their traditional lifestyle. However, rapid socioeconomic development and sociocultural changes, including fewer offspring, higher childbearing age, and shorter lactation, lead to changes in lifestyle and increased risk of breast cancer in Asia (3, 4).

Breast cancer treatments, including chemotherapy, have various side effects, leading to weakness, fatigue, increased nutritional needs, and reduced nutrient intake that may eventually lead to malnutrition (5). The prevalence of eating disorders depends on various factors, including the type of cancer and its treatment. For example, weight can be affected by edema, dehydration, tumor growth, type of cancer, social conditions of the patient, type of clinical complaint, food intake, and physical activity (6). In cancer patients, weight loss due to malnutrition is a common phenomenon that significantly impacts the treatment, follow-up, patient’s survival, and quality of life. Malnutrition and protein deficiency can aggravate hair loss in patients (7). Weight loss of at least 5% compared to pre-disease weight has been reported in one-third of breast cancer patients. In addition to the impact of weight loss on increased mortality, malnutrition is associated with a prolonged hospital stay, increased risk of unplanned hospitalization, increased disability and increased overall care costs (8).

As a result, using a standard nutritional assessment tool and a standard nutritional intervention approach is required to manage and prevent cancer-induced cachexia in patients with cancer undergoing chemotherapy (9). In 2014, the American Institute for Cancer Research reported that diet, exercise, and weight management play a pivotal role in breast cancer patients’ survival (10, 11). Findings from the Nurses’ Health Study showed that a high-fat diet during adulthood was associated with an average increase in breast cancer risk in premenopausal women (12, 13). There is also evidence that high levels of fruit and vegetable consumption may be associated with a reduced risk of breast cancer (14). Obesity after menopause increases the risk of breast cancer (15, 16). The risk of postmenopausal breast cancer is 1.5 times higher in overweight women and about two times higher in obese women. The risk of breast cancer is probably related to increased estrogen levels because adipose tissue is the largest estrogen source in women after menopause. Obesity is also a risk factor for type 2 diabetes, which is associated with an increased risk of postmenopausal breast cancer (17, 18). Therefore, a proper diet before, during, and after treatment will help the patient feel better and survive longer.

There is evidence of using different dietary components on cancer patients’ pain index, which is acclaimed by the McGill Pain Questionnaire. Khosravi et al. translated the questionnaire to Persian form and confirmed its validity and reliability (19).

The prevalence of cancer in the country is increasing, and cancer treatment consequences have a remarkable impact on the quality of patients’ lives. There are almost no studies on the effect of proper individual diet on the consequences of chemotherapy in Iran. Thus, this study aimed to evaluate the effect of individual diet therapy on the consequences of chemotherapy and quality of life as well as serum proteins, including ferritin, albumin, and hemoglobin, in breast cancer patients.

METHODS:

Participants

Seventy breast cancer patients under chemotherapy...
treatment were recruited from Motahari clinic, Shiraz, Iran. Subjects were randomly assigned into two groups (intervention for eight weeks or control) using random allocation software. Thirty-five patients per group were computed as necessary. The inclusion criteria were as follows: women with breast cancer, over 18 years, willing to participate in the study, stable, undergoing chemotherapy one to three times, not having any diseases such as CVD, diabetes, or neurodegenerative disease, not following particular treatment regimen and lack of metastatic breast cancer. All participants provided written informed consent before participation and procedure. The study was confirmed by the ethics committee of Shiraz University of Medical Sciences (ethics number: 94-01-84-10828).

Study Design
This study was an eight-week, double-blind, randomized, placebo-controlled clinical trial. The allocation was performed by a nutritionist with no clinical involvement in the study. All physicians and technicians remained blinded until the end of the analysis. Compliance was monitored through a weekly phone call.

Anthropometric measures
At the beginning and end of the trial, anthropometric indices were measured. After an overnight fast with subjects standing without shoes and wearing light clothing, body weight was measured to the nearest 0.1 kg, using Seca Electronic Weighing Scale (Seca, Hamburg, Germany). Height was recorded using a non-stretch tape measure (Seca, Hamburg, Germany) in a standing position without shoes to the nearest 0.1 cm accuracy. BMI was calculated by dividing weight (kg) by height squared (m²).

Dietary intake
Dietary intake was estimated using a 3-day 24-hour dietary recall at the baseline, midpoint, and endpoint of the trial and analyzed using Nutritionist 4 software (First Databank Inc., San Bruno, CA, USA), modified for Iranian foods.

Intervention
Patients were given a specific diet that is calculated based on the amount of energy and protein requirement and the side effects of chemotherapy (diarrhea and constipation, nausea and vomiting, oral ulcers, anorexia, and changes in taste, early satiety, dry mouth, difficulty in chewing, and devouring food). The amount of energy and protein is based on a case study of cancer patients undergoing chemotherapy in Korea in 2015 (energy: 30-35 kcal/kg; and protein: 1.2-1.6 gr/kg). The calorie division of macronutrients in the basic regimen was also determined as follows: In 1600 calorie diet: 48.37 % carbohydrate, 20.12% protein, and 31.49 % fat. In 1800 calorie diet: 48.66 % carbohydrate, 20.55 % protein, and 30.79 % fat. In 2000 calorie diet: 51.3 % carbohydrate, 19.7 % protein, and 29 % fat. In this study, we attempted to reduce chemotherapy side effects through proper diet and provide recommendations for side effects. Also, pamphlets containing routine nutritional recommendations were given to the control group simultaneously as the intervention group.

Blood Sampling and Biochemical Measurements
Seven milliliters (7 ml) fasting blood samples were collected from all patients at the baseline and endpoint of the study, put into serum separation vacutainers, and allowed to clot for 10 minutes. Serum samples were collected using centrifugation at 3000 RPM for 10 minutes at room temperature, then were quickly frozen and stored at -80°C until analyzed. Albumin, ferritin, and hemoglobin were measured.

Nutritional barriers and the quality of life
The patients completed three questionnaires containing nutritional barriers, PG-SGA, and EORTC-QLQ-C30. The purpose of this study was to identify nutritional and malnutrition barriers and quality of life in patients, their relationship with food intake, and the consequences of chemotherapy. The Nutrition Barriers
Questionnaire consists of 17 questions, separately on each of the outcomes and nutritional barriers, including patient appetite, difficulty in chewing and swallowing food, heartburn, sore throat, nausea and vomiting, dry mouth, weakness, fatigue, changes in taste and smell, premature satiety, changes in weight, dietary hatred, depression, oral ulcers, diarrhea, and constipation. The questionnaire was completed through face-to-face interviews. Concerning nutritional barriers, the scoring for each barrier is qualitative and based on the severity of the complication.

The PG-SGA questionnaire consists of two parts: 1) Medical history, including weight changes, changes in dietary intake, the persistence of gastrointestinal symptoms for more than two weeks, and changes in functional capacity; and 2) Physical examinations, including the evaluation of subcutaneous fat gain due to musculoskeletal disorders such as knee edema and ascites. For each scoring section (0–4), scores were aggregated at the end of the part, depending on symptom levels and nutritional status. Scores above nine indicated nutritional intervention requirements.

The EORTC-QLQ-C30 Quality of Life Questionnaire consists of 30 questions consisting of two parts: Functional (Physical, Emotional, Cognitive, Social, Role Playing) and Symptoms (Fatigue, Nausea and Vomiting, Pain, Dyspnea, Sleep Reduction, Appetite Reduction, Constipation, diarrhea, and financial problems). Scoring in each part ranged from 0 to 100. Higher scores in the functional part indicated better status, while in the symptom part, higher scores indicating more problems in the patient.

**Statistical Analyses**

Data were analyzed using SPSS software version 17.0 (SPSS Inc., Chicago, IL, USA), and results are expressed as mean (±SD). The normality of data distribution was assessed by a one-sample Kolmogorov-Smirnov test. Baseline variables in the two groups were compared using an independent sample t-test for quantitative variables and a chi-square test for qualitative variables. Within-group differences were analyzed using a paired sample t-test. For identifying any differences between the two groups after the intervention, an analysis of covariance (ANCOVA) was used. Results were considered statistically significant at p < 0.05.

**RESULTS:**

The mean age in the control and intervention group was 51±1.35 and 50.91±1.72, respectively. The anthropometric characteristics of patients are shown in **Table 1**. The mean weight was 65.67±11.98 and 70.16±15.91 in the control and the intervention group, respectively. There were no statistically significant differences between the groups regarding weight, height,
and BMI.

The variables were evaluated by an independent sample t-test.

According to the PG-SGA questionnaire classification, 68.5% of the patients had malnutrition at baseline. About the patients’ appetite, 11 had a good appetite, 17 had a low or moderate appetite, and 42 had a poor appetite.” in its latest global review.

The scores obtained from the PG-SGA and QLQC30 questionnaires were compared between the groups at the beginning of the intervention (Table 2).

As shown, the mean scores did not show a significant difference between the control group and the intervention group before the treatment.

Table 3 shows changes in the score of PG-SGA and QLQC30 questionnaires during the eight-week study in both groups under singular and control treatment diets.

As shown, scores of the QLQC30 and PG-SGA questionnaires in the treatment group showed a significant

| Variable                | Diet therapy group (n=35) | Control group (n=35) | P-value* |
|-------------------------|--------------------------|----------------------|----------|
| PG-SGA                  | 19.34±4.81               | 16.94±5.93           | 0.06     |
| Functional scale        | 55.26±10.50              | 61.10±14.03          | 0.53     |
| Symptom scale           | 52.44±12.74              | 50.95±16.31          | 0.67     |
| Global scale            | 46.64±13.44              | 50.21±14.64          | 0.29     |

*Independent sample T-Test, values less than 0.05 considered significant.

| Variable                | Diet therapy Group | Control Group | P-value** |
|-------------------------|--------------------|---------------|-----------|
| PG-SGA                  | Before 0.10        | After 17.91±4.88 | P-value* 16.94±5.93 | 0.001 | 14.82±4.19 | <0.001 | 19.34±4.81 | 0.06 |
| QLQC30 Functional scale | 0.02               | 58.28±12.01 | 61.10±14.03 | <0.001 | 61.80±10.83 | <0.001 | 55.26±10.50 | 0.53 |
| QLQC30 Symptom scale    | 0.94               | 51.02±15.78 | 50.95±16.31 | <0.001 | 42.82±11.04 | <0.001 | 52.44±12.74 | 0.67 |
| QLQC30 Global Scale     | 0.19               | 48.28±12.45 | 50.21±14.64 | <0.001 | 60.21±11.27 | <0.001 | 46.64±13.44 | 0.29 |

*Paired T-Test **Independent sample T-Test, values less than 0.05 considered significant.
change during the eight-week intervention. Still, in the control group, only the QLQC30 scores showed a significant difference after eight weeks. The comparison between the two groups indicated that the QLQC30 questionnaire had no significant difference at the end (Table 4). Although, the PG-SGA questionnaire, the QLQC30 symptom, and the world-scale were significantly different. The comparison between the two groups indicated that the QLQC30 questionnaire had no significant difference at the end. However, the PG-SGA questionnaire, the QLQC30 symptom, and the world-scale were significantly dif-

| Variable | Diet therapy | Group | P-value** |
|----------|--------------|-------|-----------|
|          | Before       | After | Before    | After   |          |
| Oral inflammation |            |       |          |         |          |
| Yes      | 23 (65.71)   | 6 (17.14) | <0.001 | 16 (45.71) | 24 (68.57) | 0.03 | <0.001 |
| No       | 12 (34.28)   | 29 (82.85) | 19 (54.28) | 11 (31.42) |          |       |
| Changes in the sense of taste and smell | Yes | 31 (88.57) | 13 (37.4) | <0.001 | 25 (71.42) | 26 (74.28) | 0.1 | 0.002 |
| No       | 4 (11.42)    | 22 (62.85) | 10 (28.57) | 9 (25.71)  |          |       |
| Depression | Yes | 17 (48.57) | 14 (40) | 0.54 | 12 (34.28) | 18 (51.42) | 0.33 | 0.1 |
| No       | 18 (51.42)   | 21 (60)   | 23 (65.71) | 17 (48.57) |          |       |
| Diarrhea | Never        | 17 (48.57) | 24 (68.57) | 0.03 | 23 (65.71) | 13 (37.4) | 0.01 | 0.003 |
|          | Sometimes    | 6 (18.14) | 10 (28.57) | 7 (20) | 14 (40)  |          |       |
|          | Often        | 12 (34.28) | 1 (1.75) | 5 (14.28) | 8 (22.85) |          |       |
| Constipation | Never | 19 (54.28) | 27 (77.14) | <0.001 | 21 (60)  | 16 (45.71) | 0.12 | 0.003 |
|          | Sometimes    | 8 (22.85) | 8 (22.85) | 5 (14.28) | 13 (37.4) |          |       |
|          | Often        | 8 (22.85) | 0 (0)   | 9 (25.71) | 6 (17.14) |          |       |
| Dysphagia | Never        | 11 (31.42) | 17 (48.57) | 0.007 | 18 (51.42) | 15 (42.85) | 0.12 | 0.56 |
|          | Sometimes    | 16 (45.71) | 11 (31.42) | 11 (31.42) | 11 (31.42) |          |       |
|          | Often        | 8 (22.85) | 7 (20) | 6 (17.14) | 9 (25.71) |          |       |
### Table 4. Continue...

| Variable                  | Group                  | P-value** |
|---------------------------|------------------------|-----------|
|                           | Diet therapy           |           |
|                           | Before | After | P-value* | Before | After | P-value |
| Appetite                  | Never   | 4 (11.42) | 5 (14.28) | <0.001 | 4 (11.42) | 2 (5.71) | 0.18 | 0.003 |
|                           | Sometimes | 9 (25.7) | 24 (68.57) | 9 (25.71) | 15 (42.85) |           |   |    |
|                           | Often  | 22 (62.85) | 6 (17.14) | 22 (62.85) | 18 (51.24) |           |   |    |
| Heartburn                 | Never   | 11 (31.42) | 10 (28.57) | 0.11 | 15 (42.85) | 14 (40) | 0.39 | 0.75 |
|                           | Sometimes | 15 (42.85) | 21 (60) | 11 (31.42) | 14 (40) |           |   |    |
|                           | Often  | 9 (25.71) | 4 (11.42) | 9 (25.71) | 7 (20) |           |   |    |
| Nausea                    | Never   | 4 (11.42) | 8 (22.85) | <0.001 | 4 (11.42) | 3 (8.57) | 0.03 | 0.001 |
|                           | Sometimes | 7 (20) | 26 (74.28) | 9 (25.71) | 19 (54.28) |           |   |    |
|                           | Often  | 24 (68.57) | 1 (1.75) | 22 (62.85) | 13 (37.4) |           |   |    |
| Vomiting                  | Never   | 17 (48.57) | 23 (65.71) | 0.01 | 19 (54.28) | 18 (51.42) | 0.20 | 0.24 |
|                           | Sometimes | 13 (37.4) | 11 (31.42) | 12 (32.8) | 16 (45.71) |           |   |    |
|                           | Often  | 5 (14.28) | 1 (1.75) | 4 (11.42) | 1 (1.75) |           |   |    |
| Weakness and fatigue      | Never   | 0 (0) | 0 (0) | 0.28 | 0 (0) | 0 (0) | 0.1 |
|                           | Sometimes | 5 (14.28) | 5 (14.28) | 6 (17.14) | 7 (20) |           |   |    |
|                           | Often  | 30 (85.71) | 30 (85.71) | 29 (82.85) | 28 (80) |           |   |    |
| Dry mouth                 | Never   | 2 (5.71) | 2 (5.71) | <0.001 | 1 (1.75) | 4 (11.42) | 0.07 | 0.79 |
|                           | Sometimes | 4 (11.42) | 4 (11.42) | 10 (28.57) | 20 (57.14) |           |   |    |
|                           | Often  | 29 (82.85) | 29 (82.85) | 24 (68.57) | 11 (31.42) |           |   |    |
| Early satiety            | Never   | 11 (31.42) | 15 (42.85) | 0.28 | 8 (22.85) | 10 (28.57) | 0.31 | 0.39 |
|                           | Sometimes | 17 (48.57) | 12 (34.28) | 18 (51.42) | 17 (48.57) |           |   |    |
|                           | Often  | 7 (20) | 8 (22.85) | 9 (25.71) | 8 (22.85) |           |   |    |
Different.

Table 5 shows that the level of serum albumin and hemoglobin in the intervention group significantly decreased. In contrast, the ferritin level did not change significantly during the eight weeks. The comparison between the two groups showed a significant difference in all biochemical parameters except ferritin at the end of the study.

**DISCUSSION:**

The prevalence of breast cancer is increasing dramatically, and previous studies have shown that chemotherapy affects physical health and quality of life in breast cancer patients. According to previous studies, side effects of chemotherapy interfere with proper nutrition, increase malnutrition, reduce the quality of life, and increase mortality in these patients. In the present study, we investigated the effects of an individual diet on chemotherapy outcomes and quality of life in breast cancer patients.

Some nutritional factors, including oral inflammation, changes in taste and smell, diarrhea, constipation, anorexia, nausea, weakness, fatigue, and dryness of mouth are the most prevalent side effects among patients and are considered influencing factors on patients’ food intake. These are challenges to proper nutrition that, if left unaddressed, lead to malnutrition.

A similar study conducted in Iran in 2010 by Khushnevesh et al. revealed that anorexia, dry mouth, nausea, and depression were major nutritional complaints that led to reduced food intake in cancer patients. This is similar to the data obtained from the present study. Important differences of our data with previous studies are the selection of patients with common cancers (gastro-

### Table 5. Comparison of changes in biochemical parameters of study subjects between the two groups

| Variable  | Intervention | Group | Control |
|-----------|--------------|-------|---------|
|           | Before N=35  | After N=35 | P-value<sup>a</sup> | Before N=35 | After N=35 | P-value | P-value<sup>b</sup> |
| Alb (gr/dl) | 4.06±0.23  | 4.14±0.24  | 0.001 | 4.18±0.35  | 4.12±0.30  | 0.45 | 0.014 |
| Hb (gr/dl)  | 11.66±1.74  | 12.21±1.21  | 0.001 | 11.84±1.58  | 11.91±1.19  | 0.38 | 0.003 |
| Ferritin (ng/ml) | 126.29±229.25  | 122.72±218.04  | 0.30 | 69.36±56.11  | 72.62±55.59  | 0.26 | 0.19 |

P-values less than 0.05 are considered significant.

<sup>a</sup> The variables were evaluated by paired sample t-test.

<sup>b</sup> Changes in variables after the intervention were evaluated in both groups by an independent sample t-test.
intestinal, lung, blood, breast, genitourinary cancers) and patients with no specific type of cancer (20-22). Another similar study in the Netherlands in 1997 showed that nausea and vomiting were the most common side effects of nutritional chemotherapy (23). This study differs from the present study in the following points: This study used a self-reporting questionnaire to evaluate adverse events, divided them into two categories of physical and non-physical symptoms, and also examined the prevalence of complications by age and sex. In addition to our nutritional barriers questionnaire, other validated nutritional questionnaires such as PGA-SGA and QLQ-C30 were also used to assess patients’ nutritional status and quality of life. This study showed that using an individual diet resulted in a significant reduction in symptoms and nutritional barriers. This study also showed that adherence to appropriate diet during chemotherapy leads to the preservation of patients’ weight and prevention of malnutrition and improvement of their clinical status. Evidence has shown that anorexia and inadequate nutrition lead to malnutrition in patients and affect patients’ quality of life, health status, and mortality.

A 2010 study by Gupta and Liz showed that improved nutrition over time is associated with better survival in patients with ovarian cancer (24). A critical component in assessing a patient’s nutritional status is a detailed diet history and gathering information on patients’ nutritional behaviors, which is crucial in identifying factors that may reduce a patient’s nutrient intake (25, 26). Participants in the present study were also filled participation form at the beginning of the study. At the end of the eighth week, the Nutrition Barrier Questionnaire, Quality of Life, PG-SGA, and 24-hour recalls (baseline, end of the fourth week, and end of the eighth week) were completed. Based on previous studies, dietary interventions, including modified diets following the patients’ side effects, improve the calorie increasing and protein intake (27).

It is well accepted that many malignancies are associated with a metabolic effect on the host. However, the level of metabolism affected by the vast differences in individual responses, cancer type, and the combination of treatments is challenging. A 1985 meta-analysis reported required calories in the absence of surgery or infection in cancer patients for maintenance of $1.15 \times \text{BEE}$ and storage and anabolism of $1.15 \times \text{BEE}$ (28). In patients with weight loss, calorie deficiency was also estimated at approximately 250–450 kcal per day with significant variations based on the disease’s stage and severity (29-31). The protein needed to achieve a positive nitrogen balance for people with proper nutrition, mild stress is 0.8-1 g/kg IBW. In patients with mild to moderate reduction in protein with metabolic stress, the required protein is 1.5-2 g/kg IBW (32, 33). In the present study, energy and protein levels were considered 30-30 kcal/kg and 1.2-1.6 gr/kg, respectively, based on the results of recent studies performed on chemotherapy patients. Diets were also adjusted based on nutritional needs and nutritional barriers.

In the QLQ-C30 questionnaire, a higher score in the functional part indicates the patient’s better status, and a higher score in the symptom section indicates more problems in patients. In the present study, after the individual diets, patients had higher scores in the functional part, a lower score in the symptom part, and an increase in the overall quality of life score, indicating an improvement in patients’ status at the end of eight weeks. Patients with cancer due to chemotherapy problems have a lower quality of life than healthy individuals. Using the QLQ-C30, Jarmstad et al. compared the quality of life among five groups of people with various diseases (cancer, heart disease, physical illness such as arthritis, chronic diseases such as diabetes, and visual or hearing impairment) and a group of people with no health problems. The results showed that cancer patients scored lower in the functional part of the questionnaire in terms of cognitive, physical, social,
functional, and overall quality of life compared to the other groups (34, 35). If not diagnosed and not given proper nutritional support and anticancer therapies, it can lead to increased appetite, weight loss, muscle loss, impaired immune response, increased infections, bed wounds, and decreased quality of life (36). Nirenberg and Raynard also suggested that malnutrition may lead to increased risk of complications, decreased response and tolerance to treatment, poor quality of life, reduced survival, and higher health care costs (37, 38). One of the problems in assessing the prevalence of malnutrition is that there is no specific definition. Its prevalence can vary based on the index used. Body mass index (BMI) is one of the valid nutritional status measures with the highest correlation with fat in adults (39). However, the BMI of cancer patients with malnutrition may be in the normal or overweight range, with body fat making the lean mass reduction uncertain. Therefore, BMI is not a sensitive indicator of protein-energy malnutrition, as it does not differentiate between fat and muscle depletion (40). Another limiting factor in applying BMI is fluid retention, which leads to a false increase in body weight.

Otter’s PG-SGA questionnaire is one of the ultimate tools for assessing nutritional status in cancer patients. The PG-SGA questionnaire is an easy-to-use nutritional assessment tool to identify and prioritize malnutrition in cancer patients (41, 42). In addition to measuring BMI, in this study, the PG-SGA questionnaire was used to assess patients’ nutritional status and make a more accurate assessment of their nutritional status. In the PG-SGA questionnaire, patients are divided into three levels of optimal nutrition, mild to moderate malnutrition and severe malnutrition based on weight loss, dietary intake, and symptoms of nutritional complaints, performance, and physical examinations (9). Patients’ PG-SGA scores decreased after the individual treatment regimen, indicating an improvement in the patients’ nutritional status, which was not observed in the control group, and PG-SGA scores were increased. Individuals with moderate PG-SGA scores were increased. Individuals with moderate malnutrition were 33 at the beginning of the study, which decreased to 15 after eight weeks of study.

Furthermore, the number of patients in optimal nutrition status increased from 22 to 53 at the end of the intervention. Also, 15 patients had severe malnutrition at the beginning of the study. At the end of the eight weeks, they achieved better nutritional status by maintaining weight, lowering nutritional barriers, and improving quality of life. At the end of the intervention, only two patients had severe malnutrition.

Studies have demonstrated that albumin is the best malnutrition predictor in various age groups and the most valid biochemical index applicable for protein status assessment. However, some believe that the long half-life of albumin (21 days) limits its effectiveness in monitoring fast-food changes and makes it a poor indicator of nutritional status (43, 44). It is worth noting that nutritional status and protein intake were significantly correlated with serum levels of liver protein, albumin. Studies have also shown that serum albumin levels are associated with morbidity and mortality. Therefore, it is a useful indicator in malignant patients. Serum protein provides indirect information about visceral protein levels, indicating less liver synthesis due to low intake (45). In this line, Marrine et al. reported a significant correlation between low serum albumin levels and low dietary protein intake in patients (46). Gaura et al. conducted a study in 2007 on 45 cancer patients and reported that a protein-containing diet increased serum hepatic proteins, indicating an increase in protein synthesis (47). In this regard, the present study showed that patients with 1.2-1.6 gr/kg protein in diet had higher serum albumin levels than the control group at the end of eight weeks, indicating the importance of dietary protein intake on albumin. Albumin is not only a nutrition marker but also carries medicines in these patients.
Another essential serum protein in cancer patients is ferritin, which acts as a buffer against iron deficiency and iron overload. In this regard, studies have shown that serum ferritin is abundant in tumor cells, and the increased expression levels can help to detect malignant tumors. Also, serum ferritin as a positive acute-phase protein is increased in some cases, including chronic diseases, inflammation, and malignancy. Findings indicate that ferritin expression is elevated in many malignancies, such as colon cancer, breast cancer, colorectal cancer, lung cancer, and prostate cancer (48). High serum ferritin levels in cancer patients depend on a multifactorial mechanism that includes growth and proliferation, increased necrosis, tumor cell lysis, ferritin release, and accumulation of ferric ions in reticuloendothelial cells, and consequently increased ferritin synthesis (49). One of the most common consequences of increasing iron in the body is promoting cancer cells because it is a strong oxidizer and mutagen, an inhibitor of white blood cells, and a nutrient for the rapid growth of cancer cells (50). However, the present study did not show any effect of individual diet on ferritin levels, which may be due to the nature of the disease itself on serum ferritin levels. Patients in this study were similar to those with low hemoglobin levels indicating anemia in these patients. In this regard, Kitano et al. study showed that most patients with cancer undergo anemia during treatment (51). As the present study showed, patients undergoing individual diet achieved normal hemoglobin levels at the end of eight weeks. Because many chemotherapeutic agents affect erythropoietin and may cause erythropoiesis, it may cause a high prevalence of anemia in these patients. Similarly, Barret lee et al. reported that cancer patients with low hemoglobin levels before starting treatment had a higher risk of developing anemia after chemotherapy (52). This is the first study to evaluate individual diet therapy on breast cancer patients in Iran to the best of our knowledge. However, there are some limitations such as small sample size, lack of inflammatory factors measurement, and lack of prolonged follow-up. Thus, it is suggested to consider these limitations in future studies. Also, it is suggested to evaluate the individual diet therapy effects on other cancers.

CONCLUSION:
The results of the present study showed that identifying nutritional barriers in patients with breast cancer and individual diets based on these barriers and also based on the patient’s need for energy and protein reduced the nutritional barriers affecting dietary intake and, consequently, reduced malnutrition, increased quality of life in these patients.

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CONFLICT OF INTERESTS:
The authors declare that there is no conflict of interest associated with this work.

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