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# The Effect of Educational Immune Enhancement Guidelines on Clinical Outcomes of Mastectomy Patients Undergoing Chemotherapy

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***Abstract:*** **Breast cancer is the most common invasive cancer in women, and the second main cause of cancer death among them, after lung cancer. Chemotherapy is the cancer treatment most likely to weaken the immune system. The immune system helps to fight cancer and its activation strengthen the effect of chemotherapy.**

**The aim of study: is to evaluate the effect of educational immune enhancement guidelines on clinical outcomes of mastectomy patients undergoing chemotherapy.**

**Materials and methods: The study design used was a quasi experimental survey study. A purposive sample of 60 adult female patients, age ranged 20-60 years old, with cancer and scheduled to be treated with adjuvant chemotherapy for the first time after curative surgery who met the inclusion criteria it divided randomly 30 subjects in the study group and 30 subjects in control group, the study group received chemotherapy submitted to nursing management of chemotherapy side effects and immune enhancement through (diet, exercise, and life style modification as good night sleeping for 6-8 hours, relaxation technique for relieving worry and tension) in addition to the routine hospital care, while the control group received the routine hospital care.**

**Tool of data collection: five tools are used to collect the data including; I- knowledge assessment Structured interview questionnaire, II- the Australia – modified Karnofsky performance status scale by Abernethy et al., (2005), III-The quality of life scale by brady et al., (1997), IV- Piper Fatigue scale by Piper et al., (1998) and V-Nutritional laboratory investigation assessment sheet.**

**The results of this study: revealed that after implementing the immune enhancement guidelines for the mastectomy patients undergoing chemotherapy, there was greatly improvement on the study sample quality of life, performance status of usual daily activities, fatigue level, nutritional status and lap investigations rather than the control group.**

**Conclusion: The immune enhancement through (diet, exercise, and life style modifications) is effective on the clinical outcomes of mastectomy patients undergoing adjuvant chemotherapy.**

***Keywords:*** **Chemotherapy, Clinical Outcomes, Immune Enhancement, Mastectomy.**

## 1. INTRODUCTION

Breast cancer is the most common invasive cancer in females worldwide. It accounts for 16% of all female cancers and 22.9% of invasive cancers in women. 18.2% of all cancer deaths worldwide, including both males and females, are from breast cancer. Breast cancer rates are much higher in developed nations compared to developing ones. There are several reasons for this, with possibly life-expectancy being one of the key factors breast cancer is more common in elderly

women; women in the richest countries live much longer than those in the poorest nations. The different lifestyles and eating habits of females in rich and poor countries are also contributory factors, experts believe. According to the National Cancer Institute, 232,340 female breast cancers and 2,240 male breast cancers are reported in the USA each year, as well as about 39,620 deaths caused by the disease **(Susan & Candice, 2013, Howlader, Noone, & Krapcho, 2017).**

In Egypt, 34% of Egyptian women suffer from breast cancer; "the most common type of cancer" in Egypt for women, 7,030 cases were detected in its early stages in 2016, while as many as 14,641 cases had been identified by the end of 2017. Ancology center at Mansoura University illustrate that 2324 patients were diagnosed with breast cancer in the year 2017 that consider 38.6% of all cancer cases. Awareness of the symptoms and the need for screening are important ways of reducing the risk **(Emara, 2018).**

Everyone has cancer cells; the body's immune system is designed to fight off these renegade cells before diagnosing with cancer. For this reason it is of great importance to keep the immune system in a good fighting condition. If cancer has been diagnosed, it is vital to rebuild the immune system thus the immune system has the ability to help in fighting cancer and prevent the recurrence **(Susan & Candice, 2013)**.

Breast cancer may be treated through local treatment or systemic treatment. Local treatments are used to remove or destroy cancer cells in specific area. Surgery and radiation therapy are examples of local treatments. Systemic treatments are used to destroy or control cancer cells all over the body. Chemotherapy and hormonal therapy are examples of systemic treatments. Each method of these treatments has its own rational for use as well as an individualized purpose and indication **(Smeltzer & Bare, 2009)**.

Chemotherapy, the treatment of cancer with chemical agents, is used to cure and to increase survival time. It has some selectivity for killing cancer cells over normal cells. This killing effect on cancer cells is related to the ability of chemotherapy to damage DNA and interfere with cell division. Tumors with rapid growth are most sensitive to chemotherapy.

Breast cancer itself doesn't mean that the immune system is weak. However, certain breast cancer treatments can weaken the immune system, leaving the patient more vulnerable to infection. Chemotherapy has the greatest impact on immunity, but surgery and some forms of radiation therapy can affect the immune system, too **(Russo, Linsalata and Clemente, 2013).**

Before, during, and after chemotherapy, the patient should do his best to follow the common sense ways to take care of the immune system, such as getting enough rest, eating a healthy diet, exercising, and reducing stress. Some chemotherapy medicines can reduce appetite and make patient feels tired, so it is important to manage those side effects. Many people with cancer wonder if there's anything they can do to boost their immune systems to fight off the cancer, help their bodies deal with the side effects of treatment, and lower the risk of recurrence. We don't have evidence there's anything can do to boost the immune system. However, there is a growing body of evidence that suggests that taking steps to help the immune system do its job **(Leiden, 2017).**

Therefore nutritional support, physical activity, and life style modification are increasingly recognized as fundamental concern for cancer patients undergoing chemotherapy that may strengthen the immune system and reducing the side effects of chemotherapy which in turn improve patients function and treatment efficacy by increasing tumor response and decreasing normal tissue toxicity **(Rosdahl& Kowalski, 2008, Smeltzer, 2008)**.

**Aim of study:**

Is to evaluate the effect of educational immune enhancement guidelines on clinical outcomes of mastectomy patients undergoing chemotherapy.

**Research hypothesis:**

There is a significant improvement pre and post implementing the educational guidelines, as patients who have their immune system enhanced through (diet, exercise, and life style modifications), reported a positive impact on many aspects of clinical outcomes as high quality of life, and performance status, low fatigue and expressing lower carcinogenesis biomarker (cancer stem cells).

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## 2. MATERIALS AND METHOD

**Materials:**

**Design:** A quasi experimental research design was followed.

**Setting of the study:** This study was conducted at the Oncology Center - Mansoura University Hospital.

**Subjects:** A purposive sample of 60 adult female patients, age ranged 20-60 years old, with cancer and scheduled to be treated with adjuvant chemotherapy for the first time after curative surgery who met sampling criteria recruited for this study was calculated by statistical equation; using EPI info program version 6.02 after taking into consideration the clinical incidence of 33.3 from the hospital record with the study power 80%, confidence interval of 95% and relative precision 15%, it will be divided randomly 30 subjects in study group and 30 subjects in control group. the study group received chemotherapy submitted to nursing management of chemotherapy side effects and immune enhancement through (diet, exercise, and life style modification as good night sleeping for 6-8 hours, relaxation technique for relieving worry and tension) in addition to the routine hospital care, while the control group received the routine hospital care, were selected from the above mentioned setting.

**Tools used in the study:**

**Tool I: knowledge assessment Structured interview questionnaire.**

This tool is divided into two parts:

**Part I:** patient's sociodemographic data as age, marital status, educational level, employment status, place of residence, income level, family member and number of children.

**Part II:** Patients knowledge related to breast cancer, chemotherapy side effects, and management of these side effects, immune system, and its enhancement; factors that boost the immune system and factors that weaken the immune system.

**Tool II: the Australia – modified Karnofsky performance status scale by Abernethy et al., (2005)**

It was developed by **Abernethy et al., (2005),** and modified and translated into Arabic by the researcher to assess the patient's ability to perform usual activities, and evaluating patient's progress after therapeutic procedure. It is used most commonly in the prognosis of cancer therapy, usually after chemotherapy.

**Tool III: The quality of life scale by brady et al., (1997)**

It was developed **by brady et al., (1997)** and modified and translated into Arabic by the researcher to assess patients quality of life from physical, social, psychological, and spiritual wellbeing.

**Tool IV: Piper Fatigue scale by Piper et al., (1998)**

It was developed by **Piper et al., (1998)** and modified and translated into Arabic by the researcher to assess patient's experience of unusual or excessive tiredness during illness, receiving treatment, or recover from illness.

**Tool V: Nutritional and laboratory investigation assessment sheet.**

It was developed by the researcher after reviewing the related literature **(Johnstone et al., 2009)** to identify the patient nutritional status it include dietary history, Anthropometric measurements and laboratory investigations. It includes the following:

**a) Dietary history:** information about number of meals per day, regularity of meals, type of meat, chicken, vegetables, and fruits taken. Methods of cooking, type of food buying practices, and nutritional supplements that improve the immune system.

**b)Anthropometric measurements:** Anthropometric measurements include current body weight, height in cm, and body mass index (BMI) to determine if the patient is underweight or over weight. The body mass index is calculated as person's weight in kilograms divided by their height in meters squared ($Kg/m^2$) and ranged according to **(World Health Organization, 2014)**:

-BMI= (weight in kilograms) / (height in meters²).

-Underweight: BMI was lower than 18.5 (Kg/m²).

-Normal: BMI was between18.5 - 24.9 (Kg/m²).

-Overweight: BMI was between 25 -29.9 (Kg/m²).

-Obese: BMI was 30 or higher (Kg/m²).

**c) laboratory investigations:**

It included the following laboratory tests: hemoglobin, hematocrit, blood urea, serum creatinine, serum albumin, and Laboratory assessment of Potential Carcinogens Biomarker (Cancer stem cells): it included the laboratory assessment of CA15.3 to evaluate the residual Cancer stem cells.

**Methods:**

1. An official permission was taken from the research ethics committee of the Faculty of Nursing at Mansoura University to the director of Oncology Center at Mansoura University Hospital, to conduct the study after explaining its purpose as well as its expected outcomes.
2. The tool was developed by the researcher after reviewing the relevant literature and tested for its validity by jury of 8 expertises in the field.
3. Pilot study was conducted on 10% of total number of female patients with cancer and undergoing adjuvant chemotherapy to test the validity and reliability of the tools they were then excluded from the study. Reliability test was made by using Cronbach's (alpha= .85)

**Ethical consideration:**

Prior to the study, verbal consent was obtained from each participating patient enrolment in to the study after clarification of the nature and purpose of the study. The investigator emphasized that participation is absolutely voluntary and confidential. Anonymity, privacy, safety and confidentiality were absolutely assured throughout the whole study. Each participant has the right to withdraw from the study at any time.

**Handling and analysis of data:**

The raw data were coded and entered into SPSS system files (SPSS package version 18). Analysis and interpretation of data were conducted. The following statistical measures were used:

- Descriptive statistics including frequency, distribution, mean, and standard deviation were used to describe different characteristics.
- Kolmogorov – Smirnov test was used to examine the normality of data distribution.
- Univariate analysis using Chi-Square test was used to test the significance of results of qualitative variables.
- Linear correlation was conducted to show correlation between knowledge, attitude and practice scores among the studied health care workers.
- The significance of the results was at the 5% level of significance.

## 3. RESULTS

**Table (1):** Represents sociodemographic data of the studied sample, there were half and less than half (50% & 46.7%) of the study and control group respectively had age ranged between 40 – 49 years old, and slightly more than three quarter (76.7%) of the sample in the study group and majority (86.7%) of the sample in the control group were married. Most of the sample (70% &73.3%) of the study and control group respectively resided rural area. Regarding to their educational level there were half (50%) of the study group and slightly less than half (46.7%) of the control group were illiterate. The majority of the study and control group live with their families (90% & 83.3%) respectively. More than three quarter (76.7%) of women in the study group, and majority (90%) of the control group were housewives. According to the

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number of their children; above three quarter (76.7%) of the study group and more than half (56.7%) of the control group had three or more children. Two thirds (66.7%) of study group and less than three quarter (73.3%) of the control group have enough income.

**Table 1: Socciodemographic characteristic of the studied sample**

| Sociodemograghic data | Study group (N=30) | | Control group (No =30) | | $X^2$ | P - value |
|---|---|---|---|---|---|---|
| | No | % | No | % | | |
| **Age grouping (years):-** | | | | | | |
| 20-39 | 2 | 6.7% | 3 | 10.0% | 0.380 | .827 |
| 40-49 | 15 | 50.0% | 14 | 46.7% | | |
| 50-60 | 13 | 43.3% | 13 | 43.3% | | |
| **Marital status:-** | | | | | | |
| Single | 0 | 0% | 0 | 0% | 1.002 | .317 |
| Married | 23 | 76.7% | 26 | 86.7% | | |
| Widow | 4 | 13.3% | 3 | 10.0% | | |
| Divorced | 3 | 10.0% | 1 | 3.3% | | |
| **Residence** | | | | | | |
| Rural | 21 | 70.0% | 22 | 73.3% | 0.082 | .605 |
| Urban | 9 | 30.0% | 8 | 26.7% | | |
| **Educational level:-** | | | | | | |
| Illiterate | 15 | 50.0% | 14 | 46.7% | 1.587 | .0662 |
| Read and write | 3 | 10.0% | 5 | 16.7% | | |
| secondary education | 9 | 30.0% | 10 | 33.3% | | |
| Academic education | 3 | 10.0% | 1 | 3.3% | | |
| **Living status** | | | | | | |
| Live with family | 27 | 90.0% | 25 | 83.3% | 0.577 | .448 |
| Live alone | 3 | 10.0% | 5 | 16.7% | | |
| **Occupation :-** | | | | | | |
| Student | 1 | 3.3% | 0 | 0% | 0.577 | .448 |
| Employee | 5 | 16.7% | 3 | 10.0% | | |
| House wife | 23 | 76.7% | 27 | 90.0% | | |
| Retired | 1 | 3.3% | 0 | 0.0% | | |
| **Number of children:** | | | | | | |
| None | 1 | 3.3% | 4 | 13.3% | | |
| One | 1 | 3.3% | 3 | 10.0% | 3.791 | 0.285 |
| Two | 5 | 16.7% | 6 | 20.0% | | |
| Three or more | 23 | 76.7% | 17 | 56.7% | | |
| **Income:** | | | | | | |
| Not enough | 10 | 33.3% | 8 | 26.7% | 2.584 | .108 |
| Enough | 20 | 66.7% | 22 | 73.3% | | |

**Table (2):** Represents comparison between the study group and control group regarding to the patients' total knowledge of breast cancer, chemotherapy, side effects of chemotherapy and immune system, there were highly statistically significant differences between the study and control group post implementing of the educational guidelines, at the 1st, 3rd, and 6th sessions of chemotherapy regarding to their total knowledge score scale, where p-value were (<0.001) at the three sessions.

**Table (2): Comparison between the study group and control groups regarding to the total knowledge score scale**

| Total knowledge score scale | Study group | | Control group | | Student`s t test | |
|---|---|---|---|---|---|---|
| | No | % | No | % | No | % |
| **Pre** | 28 | 93.3 | 25 | 83.3 | 1.839 | 0.399 |
| Poor (<50%) | 2 | 6.7 | 4 | 13.3 | | |
| Average (50%-75%) | 0 | 0.0 | 1 | 3.3 | | |
| Good (> 75%) | | | | | | |
| **After 1st session** | 0 | 0.0 | 20 | 66.7 | 33.227 | <0.001 |

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| | | | | | | |
|---|---|---|---|---|---|---|
| Poor (<50%)<br>Average (50%-75%)<br>Good (> 75%) | 16<br>14 | 53.3<br>46.7 | 9<br>1 | 30.0<br>3.3 | | |
| **After 3rd session** Poor (<50%)<br>Average (50%-75%)<br>Good (> 75%) | 0<br>2<br>28 | 0.0<br>6.7<br>93.3 | 21<br>8<br>1 | 70.0<br>26.7<br>3.3 | 49.738 | <0.001 |
| **After 6th session**<br>Poor (<50%)<br>Average (50%-75%)<br>Good (> 75%) | 0<br>0<br>30 | 0.0<br>0.0<br>100.0 | 21<br>8<br>1 | 70.0<br>26.7<br>3.3 | 56.129 | <0.001 |

**Table (3):** Represents comparison between the study and control group regarding to Australia – modified Karnofosky performance. The table shows numbers and percentages distribution of the study and control group regarding to performing usual daily activities and also the comparison between both groups. There was no statistically significant difference between study group and control group pre implementing the educational guidelines (before the first cycle of chemotherapy) and also after the frist cycle of chemotherapy (p=.987). While, there was highly statistically significant difference between both groups after the 3rd and 6th sessions of chemotherapy (p<0.001*), as after the 3rd session there were (56.7%) of the study group were at score 90 (Perform usual daily activities, but with mild tiredness) while more than one third (36.7%) of the patients in the control group were at score 60 (unable to perform usual daily activities and require stronger help), and after the 6th session of chemotherapy there were slightly less than three quarter (73.3%) of the patients in the study group were at score 90 (Perform usual daily activities, but with mild tiredness) in comparison to only (6.7%) of the control group who had the same score.

**Table (3): Comparison between the study and control groups regarding to Australia – modified Karnofosky performance**

| Scores of Karnofosky scale | Study group (N=30) | | | | | | | | Control group (No =30) | | | | | | | | $X^2$ | P - value |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | pre | | After 1st | | After 3rd | | After 6th | | pre | | After 1st | | After 3rd | | After 6th | | | |
| | No | % | No | % | No | % | No | % | No | % | No | % | No | % | No | % | | |
| Score 10 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | | |
| Score 20 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | Pre= .834 | Pre=.0987 |
| Score 30 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | After1=.659 | After1= .0564 |
| Score 40 | 1 | 3.3 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 3.3 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | Aftetr3= 19.739 | Aftetr3= <0.001 |
| Score 50 | 4 | 13.3 | 1 | 3.3 | 0 | 0.0 | 0 | 0.0 | 6 | 20.0 | 0 | 0.0 | 1 | 3.3 | 1 | 3.3 | After6= 34.667 | After6= <0.001 |
| Score 60 | 6 | 20.0 | 3 | 10.0 | 1 | 3.3 | 0 | 0.0 | 8 | 26.7 | 5 | 16.7 | 11 | 36.7 | 8 | 26.7 | | |
| Score 70 | 5 | 16.7 | 1 | 3.3 | 4 | 13.3 | 3 | 10.0 | 3 | 10.0 | 5 | 16.7 | 9 | 30.0 | 12 | 40.0 | | |
| Score 80 | 14 | 46.7 | 16 | 53.3 | 8 | 26.7 | 3 | 10.0 | 12 | 40.0 | 12 | 40.0 | 7 | 23.3 | 7 | 23.3 | | |
| Score 90 | 0 | 0.0 | 9 | 30.0 | 17 | 56.7 | 22 | 73.3 | 0 | 0.0 | 8 | 26.7 | 2 | 6.7 | 2 | 6.7 | | |
| Score 100 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 2 | 6.7 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | | |

**Score 100** Perform usual daily activities without any health problem

**Score 90** Perform usual daily activities**,** but with mild tiredness.

**Score 80** Perform usual daily activities**,** but with sever tiredness**.**

**Score 70** unable to perform usual daily activities and require help.

**Score 60** unable to perform usual daily activities and require stronger help.

**Score 50** Unable to perform usual daily activities and require great help.

**Score 40** Stay more than half the time at the bed.

**Score 30** Stay most of the time at the bed.

**Score 20** Stay all the time at the bed.

**Score 10** In coma.

**Table (4)**: Represents comparison between the study and control groups regarding to the Total Piper Fatigue Scale, there was no statistically significant difference between study group and control group pre implementing of the educational guidelines (before the 1st session of chemotherapy). The majority (86.7%) of both groups have had sever fatigue. While this fatigability for the study group was improved to be moderate after the first 1st session in more than half of the patients (53.3%) while there were exactly one third (33.3%) of patients in the control group who had moderate fatigue. After the 3rd session of chemotherapy, there was no patients of the study group had sever fatigue, while there were more than two thirds (40%) of the control group had sever fatigue, and after the 6th session, the majority (90%) of patients in the study group had mild fatigue in comparison to only (3.3%) of the control group who had mild fatigue. There was highly statistically significant difference between the study group and control group regarding to level of fatigue post implementing the educational guidelines. P-values were (<0.001*) after the 1st, 3rd and 6th sessions of chemotherapy)

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**Table (4): comparison between study and control groups regarding to the Total Piper Fatigue Scale**

| Fatigue scale | Study group (N=30) | | | | | | | | Control group (No =30) | | | | | | | | $X^2$ | P - value |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | pre | | After 1st | | After 3rd | | After 6th | | pre | | After 1st | | After 3rd | | After 6th | | | |
| | No | % | No | % | No | % | No | % | No | % | No | % | No | % | No | % | | |
| Mild | 0 | 0.0 | 0 | 0.0 | 14 | 46.7 | 27 | 90.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 3.3 | Pre= .865 | Pre=.567 |
| Moderate | 4 | 13.3 | 16 | 53.3 | 16 | 53.3 | 3 | 10.0 | 4 | 13.3 | 10 | 33.3 | 18 | 60.0 | 19 | 63.3 | After1= 23.469 | After1= <0.001 |
| Sever | 26 | 86.7 | 14 | 46.7 | 0 | 0.0 | 0 | 0.0 | 26 | 86.7 | 20 | 66.7 | 12 | 40.0 | 10 | 33.3 | Aftetr3= 26.118 | Aftetr3= <0.001 |
| | | | | | | | | | | | | | | | | | After6= 50.769 | After6= <0.001 |

**Table (5):** Represents comparison between the study and control groups regarding to quality of life, as according to physical fitness, the physical fitness was improved after the 6th cycle in the study group to be (18.2±2.4) while deteriorated in the control group to be (8.5±2.0) and there was highly significant difference between both groups after the 6th cycle of chemotherapy (p<0.001*).

According to social interests, there was highly significant difference between both groups after the 6th cycle of chemotherapy (p=0.001*) as the mean score of study group after the 6th cycle was (17.6±2.0) compared to (13.5±3.5) for the control group.

According to psychological wellbeing there was highly statistically significant difference between both groups after the 6th session of chemotherapy (p<0.001*) as the mean score of study group after the 6th cycle was (12.9±2.2) compared to (5.5±2.3) for control group.

According to functional abilities, there was highly significant difference between both groups after the 6th session of chemotherapy (p<0.001*) as the mean score for the study group after the 6th cycle was (36.8±4.1) compared to (36.8±4.1) for the control group.

**Table (5): Comparison between the study and control group regarding to quality of life**

| Quality of life | Study group (N=30) | Control group (No =30) | $X^2$ | P - value |
|---|---|---|---|---|
| | Mean ±SD | Mean ±SD | | |
| **Physical fitness** | | | | |
| Pre | | | | |
| After 1st | 15.0±3.4 | 15.9±1.6 | 1.210 | .0231 |
| After 3rd | 16.6±2.8 | 15.5±20 | 1.781 | 0.080 |
| After 6th | 18.2±2.3 | 11.5±1.9 | 12.236 | <0.001 |
| **Social interests** | 18.2±2.4 | 8.5±2.0 | 16.242 | <0.001 |
| Pre | | | | |
| After 1st | | | | |
| After 3rd | 15.7±2.8 | 14.7±3.2 | 1.329 | 0.189 |
| After 6th | 16.4±2.9 | 14.6±3.6 | 2.064 | 0.044 |
| **Psychological wellbeing** | 17.3±2.0 | 14.0±3.6 | 4.322 | <0.001 |
| Pre | 17.6±2.0 | 13.5±3.5 | 5.623 | <0.001 |
| After 1st | | | | |
| After 3rd | | | | |
| After 6th | | | | |
| **Functional abilities** | 12.4±2.1 | 12.6±1.9 | 0.387 | 0.700 |
| Pre | 12.9±2.9 | 10.4±2.2 | 3.767 | <0.001 |
| After 1st | 12.8±2.1 | 7.1±2.4 | 9.719 | <0.001 |
| After 3rd | 12.9±2.2 | 5.5±2.3 | 12.740 | <0.001 |
| After 6th | | | | |
| | 32.6±4.0 | 27.1±3.8 | 0.526 | 0.601 |
| | 32.4±3.9 | 26.1±3.9 | 6.304 | <0.001 |
| | 37.1±4.4 | 25.0±3.7 | 11.538 | <0.001 |
| | 36.8±4.1 | 22.9±3.6 | 14.018 | <0.001 |

**Table (6):** Represents comparison of the laboratory findings between the study and control groups, as the Mean±SD of laboratory investigation after the 6th session of chemotherapy for hemoglobin were (11.0±1.4& 8.9±1.5) for the study group and control group respectively, Hematocrit were (0.42 ±0.04& 0.36 ±0.12) respectively, WBCs count ($x10^3$ cells/mm3) were (6.9 ±1.6 & 5.0 ±1.9) respectively , and Platelets count ($x10^3$cells/mm3) were (253.1 ±43.3 & 306.5 ±94.4) respectively with highly statistically significant difference for the study group compared to the control group (p=0.001* after 6th session).

Also the table shows greatly improvement of the carcinogenesis biomarker (CA15.3) for the study group compared to the control group post implementing of the educational guidelines (after the 6th session of chemotherapy) where p-value (<0.001*).

**Table (6): Comparison of the laboratory findings between the study and control groups**

| | Study group Mean ±SD | Control group Mean ±SD | Student`s t test t | p |
|---|---|---|---|---|
| **Hemoglobin (gm/dl)** | | | | |
| Pre | 9.8 ±1.0 | 10.1 ±1.4 | .0642 | .0980 |
| After 1st session | 9.5 ±0.8 | 9.8 ±1.5 | .664 | .0887 |
| After 3rd session | 10.8 ±1.0 | 9.4 ±1.0 | 5.263 | <0.001 |
| After 6th session | 11.0 ±1.4 | 8.9 ±1.5 | 8.361 | <0.001 |
| **Hematocrit** | | | | |
| Pre | 0.35 ±0.06 | 0.38 ±0.05 | 2.346 | 0.022 |
| After 1st session | 0.34 ±0.05 | 0.37 ±0.05 | 2.155 | 0.035 |
| After 3rd session | 0.38 ±0.04 | 0.34 ±0.04 | 2.624 | 0.011 |
| After 6th session | 0.42 ±0.04 | 0.36 ±0.12 | 3.368 | <0.001 |
| **WBCs count ($x10^3$ cells/$mm^3$)** | | | | |
| Pre | 5.8 ±1.9 | 6.4 ±2.1 | 1.165 | 0.249 |
| After 1st session | 5.6 ±1.7 | 6.1 ±1.8 | 1.002 | 0.321 |
| After 3rd session | 6.1 ±1.8 | 5.5 ±1.8 | 1.227 | 0.225 |
| After 6th session | 6.9 ±1.6 | 5.0 ±1.9 | 4.304 | <0.001 |
| **Platelets count ($x10^3$ cells/$mm^3$)** | | | | |
| Pre | 221.3 ±55.0 | 249.9 ±61.8 | 1.893 | 0.063 |
| After 1st session | 217.9 ±50.3 | 252.1 ±64.3 | 2.289 | 0.026 |
| After 3rd session | 237.5 ±45.7 | 274.9 ±62.6 | 2.388 | 0.020 |
| After 6th session | 253.1 ±43.3 | 306.5 ±94.4 | 2.814 | 0.007 |
| **CA15.3** | | | | |
| Pre | 126.2±46.7 | 131.2±66.6 | 0.334 | .739 |
| After 6th session | 28.9±123.8 | 88.8±45.4 | 6.897 | <0.001 |

## 4. DISCUSSION

Breast cancer is the most common invasive cancer in women. Although cancer treatments and therapies are improving all the time, breast cancer remains one of the main causes of death in women, with the majority of these deaths being attributed to the spread of the tumor. Immune system enhancement is very important for breast cancer patients to fight off the cancer, help their bodies deal with the side effects of treatment, and lower the risk of recurrence. There are essential ways to boost the immune system do its job. Common sense practices such as getting enough sleep, eating healthy foods, exercising, and reducing stress all appear to play some role in immune system function **(Bedognetti, et al., 2016, Hendrickx, et al., 2017) .**

Discussion of the study results will cover six main parts as follows:

- The first part concerned with representation of socio-demographic characteristics of the studied groups and patient's assessment regarding present medical history and health state.

- The second part concerned with patients' knowledge of both groups regarding to (breast cancer, chemotherapy and its side effects, and the immune system) pre educational guidelines (before the 1st session of chemotherapy) & after implementing of the educational guidelines (after 1st, 3rd and 6th session of chemotherapy).

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- The third, fourth, and fifth parts represented the effect of immune enhancement on the clinical outcomes of mastectomy patients undergoing chemotherapy as follow;

- The third part concerned with the patients' usual daily activities of both groups by Australia – modified Karnofosky performance pre educational guidelines (before the 1st session of chemotherapy) & after implementing of the educational guidelines (after 1st, 3rd and 6th session of chemotherapy).

- The fourth part concerned with patients' fatigue level pre educational guidelines (before the 1st session of chemotherapy) & after implementing of the educational guidelines (after 1st, 3rd and 6th session of chemotherapy) by Piper Fatigue Scale.

- The fifth part concerned with patients' quality of life pre educational guidelines (before the 1st session of chemotherapy) & after implementing of the educational guidelines (after 1st, 3rd and 6th session of chemotherapy).

- And finally the sixth part concerned with patients' nutritional status and laboratory investigations pre educational guidelines (before the 1st session of chemotherapy) & post implementing of the educational guidelines (after 1st, 3rd and 6th session of chemotherapy).

**Part I: Sociodemographic characteristics**

The results of the current study revealed that half and less than half of the study and control group respectively had age at the fourth decade. Interestingly, in the same line, **Ahmed (2015), Abdl Alalem (2013), Auvinen,et al, (2010), and Elmadbouh (2010)** found that most of the participant breast cancer patients in the study and control group had age at the fourth decade. This may be due to females exposed to more stresses, nutritional deficiency, obesity and hormonal changes in that age. This is not comparable with other studies which were done in the regional and other countries worldwide. For instance, in a study which was done in Gaza/Palestine for health promotion of patients with breast cancer, the highest proportion was in the at the fifth decade **(Alhamss et al., 2014)**.

In another study that was undertook in Bahrain which measured the quality of life of Bahraini women with breast cancer, showed that the mean ages of participants were at the fifth decade with highest level in age group (≤50) years old **(Jassim and Whitford, 2013)**. However, in a study which was done in South Korea, age group of (45-49) years old were more affected **(Oh et al., 2016)** but in UK, and USA the most prevalent age of breast cancer were above 50 years old **(DeSantis et al., 2015 ; Woods et al., 2016).** In addition, in Japan and China breast cancer was common in the age of over 50 years old **(Toyoda et al., 2016; Wen et al., 2016).** In a study which was carried out in Nigeria among patients with breast cancer, the majority of them were in (50-59) years old **(Adenipekun et al., 2012)** [19].

In relation to the marital status mostly of the women in the study group and the majority of the women in the control group were married, this is consistent with **Dang, Amiruddin, Lai and Chan (2017) , Ahmed (2015), Abdl Alalem (2013), and Elmadbouh (2010)** who found that the majority of the study and control group were married. This may be due to as the women that included in the study were from 20-60 years old "the productive life" so it is normally for the majority of them to be married. This may indicate that marriage associated problems may result in cancer either by increasing work load, responsibilities and stress.

The study revealed that, mostly of the women in the study group, and the majority of the control group were housewives. This result is in agreement with the findings of **Dang**, **Amiruddin, Lai and Chan (2017), Ahmed (2015), Abdl Alalem (2013), and Elmadbouh (2010)** who reported that the majority of their studied patients were housewives.

In relation to educational level, half of the study group and slightly less than half of the control group were illiterate. This result contradict with **Ahmed (2015) and Abdl Alalem (2013)** who have most of the patients with secondary education and also contradict with **Auvinen, et al, (2010)** [12] who had the most of their participant patients with university education. This difference may be due to the difference between countries regarding awareness and culture. This level of education may affect the level of awareness and understanding regarding the preventive information of the cancer and also the importance of its early detection through the scheduled follow up.

The current study revealed that, most of the women of the study and control group resided rural area and the majority of the women in both groups live with their family. This agrees with **Ahmed (2015), Abdl Alalem (2013), and Elmadbouh (2010)** who found that most of patients reside rural areas and live with their family.

According to the number of their children, more than three quarter of the women in the study group and more than half of the women in the control group had three or more children, these results consistent with the finding of **Ahmed (2015), Abdl Alalem (2013)** whose study sample had three or more children.

In relation to the income of the studied sample, two thirds of the study group and less than three quarter of the control group have enough income, this in agreement with **Ahmed (2015), Abdl Alalem (2013)** in which their study sample had also enough income.

The majority of the study group and two thirds of the control group were in the third stage of their disease. This result is agree with the study done by **Ahmed (2015),** who had the mostly of the study sample in the third stage, but contradict with **Auvinen et al., (2010)** whose patients in the study group with early stage of disease and the length of the disease occurs within 1-3 years in most of patients.

**Part II: patients' fatigue level pre educational guidelines (before the 1st session of chemotherapy) & after implementing of the educational guidelines (after 1st, 3rd and 6th session of chemotherapy) by Piper Fatigue Scale.**

The results of our study revealed that, there was no statistically significant difference between study group and control group pre implementing of the educational guidelines (before the 1st session of chemotherapy), As the majority of both groups have had sever fatigue, this fatigability is due to the mastectomy operation itself before chemotherapy, also the fatigue level score high after the 1st session as a side effect of chemotherapy. This result in line with **Curt et al., (2000)** who stated that fatigue is a common problem of chemotherapy treatment which can't be preserved by rest or sleep and affects both physical and psychological aspects and also quality of life. **Bardwell and Ancoli-Israel (2008)** also reported that fatigue is a common and disabling symptom in breast cancer patients which called cancer related fatigue, and overlaps with sleepiness and depressed mood. Also in the same line **Giuliano, Connolly & Edge (2017), Bardwell, Ancoli-Israel Dimsdale (2007)** demonstrated that people getting chemotherapy in cycles, fatigue often gets worse in the first few days and then gets better until the next treatment, when the pattern starts again, fatigue usually gets worse as the treatment goes on.

This fatigability of the study group was improved to be moderate after the first 1st session in more than half of the patients, while there were exactly one third of patients in the control group who had moderate fatigue. After the 3rd session of chemotherapy, there was no patients of the study group had sever fatigue, while there were more than two thirds of the control group had sever fatigue. There was highly statistically significant difference between the study group and control group regarding to the level of fatigue post implementing the educational guidelines, after the 1st, 3rd and 6th sessions of chemotherapy). The fatigue level improved for the study group as result of the educational guidelines which had the patient's immune system enhanced through proper diet, moderate exercise and sleeping enough time at night, the educational guidelines also concerned with managing the fatigue as a side effect of chemotherapy. On the other hand the patients in the control group still had high fatigue level as a result of chemotherapy side effect. Our results in agreement with **Vashistha, Singh, Kaur, Prokop & Kaushik**, **(2016)** who illustrated that increasing physical activity by exercise and relaxation help in releasing fatigue and improve quality of life in cancer patients. Additionally **Allen et al., (2008)** reported increased ranges of motion exercise are implicated in muscle fatigue, Furthermore **Meneses-Echávez, González-Jiménez, Correa-Bautista, Valle & Ramírez-Vélez (2015), Meneses-Echavez, Gonzalez-Jimenez, Ramirez-Velez (2015),** found exercise is a safe and effective intervention in the management of fatigue in cancer patients undergoing active treatment.

**Part V: patients' quality of life pre educational guidelines (before the 1st session of chemotherapy) & after implementing of the educational guidelines (after 1st, 3rd and 6th session of chemotherapy).**

According to physical fitness pre implementing the educational guidelines (before the first session of chemotherapy) there was no statistically significance difference between both groups. The physical fitness was improved after the 6th cycle in the study group, while deteriorated in the control group. As a result of enhancing patient's immunity and effective management of chemotherapy side effects through the educational guidelines, the physical fitness improved for the study group rather than the control group.

According to social interests, there was highly significant difference between both groups after the 6th cycle of chemotherapy. This improvement of social interests was due to encouraging the patients of the study group to improve social interests and alleviate any stress they can face and this is one of the educational guidelines components of immune enhancement.

According to psychological wellbeing, there was highly statistically significant difference between both groups after the 6th session of chemotherapy. The improvement of the psychological wellbeing is due to the improvement of both physical fitness and social interests, also this is because enhancing the patients to be happy and alleviate any stressors and teach them how to cope with any stress also the management of chemotherapy side effects played an important rule for the psychological wellbeing of the study group, in contrast in my opinion the psychological wellbeing go the control group bad because of being diagnosed with breast cancer and also due to the side effects of chemotherapy which had a lot of embracement side effects as hair loss, and may be also due to losing of a sexual part which is the breast however the study group was educated how to deal with these effects.

According to functional abilities there was highly significant difference between both groups after the 6th session of chemotherapy. In my opinion the functional abilities of the study group improved due to the effect of enhancing the immune system, although the functional abilities of the control group deteriorated due to bad nourishment as a result of anorexia, vomiting, anemia which is common side effects of chemotherapy.

The results mentioned above in line with **El-Shamy (2016)** who showed that Quality of Life data between intervention and control groups were similar and balanced between the intervention and control groups before the intervention and there were no significant differences while there were statistically significant differences between groups post intervention through Providing education to patients before the start of chemotherapy and prepares them for treatment and, in the long term, may improve coping strategies when dealing with the illness. This approach may assist patients in avoiding unnecessary side effects and lead to improved patient outcomes.

This findings is also supported by **Chean , Zang, Lim and Zulkefle (2016)** who cleared that chemotherapy reduced the quality of life of breast cancer patients. Management of chemotherapy-induced loss of appetite, diarrhea, nausea and vomiting should be improved for a better outcome. in the same line **Mishra, Scherer, Snyder, Geigle & Gotay (2015)** stated that, regural exercise, mangement of fetigue and adequate diet is important for improving health-related quality of life from diagnosis through active cancer treatment. Additionally **Hwang, Chang and Park (2013)** reported that breast cancer patients who underwent adjuvant chemotherapy experienced significantly worse quality of life as they experienced significantly poor physical, emotional, social/family, functional well-being and higher breast cancer specific concerns. These results suggest that health care professionals may need to address long-term as well as short-term chemotherapy side-effects and intervene accordingly to enhance quality of life of breast cancer patients. **Lôbo, Fernandes, Almeida, Carvalho and Sawada (2014)** stated that Women with breast cancer showed changes in the following domains; financial, emotional, sexual satisfaction and future prospects. The most frequently mentioned symptoms were fatigue, insomnia and loss of appetite. These findings are in agreement with our study.

**According to the laboratory findings between the study and control groups.**

The laboratory investigations as (Hemoglobin, Hematocrit, WBCs and Platelets) after the 6th session of chemotherapy were improved for the study group rather than the control group. Also there was greatly improvement of the carcinogenesis biomarker (CA15.3) for the study group compared to the control group post implementing of the educational guidelines (after the 6th session of chemotherapy). In the same line **Ab-Aalem (2013)** stated that there was a significant improvement in patients' investigation following applying an educational program for the study group in comparison to the control group.

from the forgoing discussion, it can be concluded that the effect of teaching about chemotherapy side effects and immune enhancement through diet, exercise, and life style modification have a positive effect on the improvement of patients' physical, functional abilities and treatment efficacy.

## 5. CONCLUSION

Based on the findings of the present study, it could be concluded that:

Enhancing the immune system through the educational immune enhancement guidelines is very important for mastectomy patients undergoing chemotherapy, and this will occur through, well balanced diet that containing all essential nutrients which has the ability to strengthen the immune system, moderate exercise as jogging from 20-30 minutes every day/5days per week, and also through life style modifications as sleeping 8 hours at night and following measures that relieve stress

and increase happiness, additionally managing chemotherapy side effects. Mastectomy Patients undergone educational immune enhancement guidelines reported high quality of life, high performance status for usual activities, low fatigue, improvement of their nutritional status and express lower carcinogenesis biomarker (cancer stem cells).

## 6. RECOMMENDATION

Based on the findings and conclusions drawn from the study, the following recommendations are derived and suggested:

1. Providing counseling for mastectomy patients undergoing adjuvant chemotherapy on managing the side effects that related to their chemotherapy treatment.
2. Periodical educational guidelines for the patients with breast cancer and undergone adjuvant chemotherapy about components of immunity enhancement through proper diet, moderate exercise and life style modification.
3. A booklet with all important information about managing chemotherapy side effects, and component on immune enhancement should be distributed for each mastectomy patients undergoing adjuvant chemotherapy.
4. Further researches are needed with large sample size for generalization of the results to population of mastectomies patients undergoing adjuvant chemotherapy.

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