

## Effectiveness of nursing intervention designing protocol in improving knowledge and adherence among women with breastcancer regarding oral hormonal therapy

Neama Fosdok William<sup>1</sup>, Shalabia El-Sayed abozead<sup>2</sup>, Zienab Abd-El-lateef Mahammad<sup>3</sup>, Salah Mabrouk Khallaf<sup>4</sup> & Asmaa Sayed Abd Almageed<sup>5</sup>

<sup>1</sup>. Mastar Degree of Medical Surgical Nursing, Faculty of Nursing, at Assiut University Egypt,

<sup>2</sup>. Professor of Medical Surgical Nursing, Faculty of Nursing, Assiut University Egypt,

<sup>3</sup>. Professor of Medical Surgical Nursing, Faculty of Nursing, Assiut University Egypt,

<sup>4</sup>. Assistant Professor of Medical Oncology and Hematological Oncology South Egypt Cancer Institute, Assiut, Egypt

<sup>5</sup>. Assistant Professor of Medical Surgical Nursing, Faculty of Nursing, Assiut University, Egypt

### Abstract:

**Background:** Oral hormonal medication is an essential part of the management of breast cancer patients. Nurse intervention is important in the improvement of knowledge and the self-reported level of adherence to hormonal therapy among women with breast cancer. **Aim:** To evaluate the Effectiveness of nursing intervention designing protocol in Improving knowledge and adherence among women with breast cancer regarding oral hormonal therapy. **Subjects and Method:** Quasi-experimental single-group pre-post-test design was utilized. A convenient number of 200 adult women with the diagnosis of metastatic breast cancer were included in this study, there are ranged from (18-65) years, new receiving oral hormonal therapy, from the inpatient department and outpatients' clinic at South Egypt Cancer Institute of Assiut University hospitals. A structured interviewing questionnaire included demographic, medical data, Knowledge assessment, and an adherence scale was used. Nursing intervention protocol was carried out over 2 months for patients at follow-up. **Results:** All of them (100%) were females, the majority of them (98%) were married, all studied patients (100%) achieve good knowledge, and 90% of studied patients achieved medium to high scores regarding compliance for oral hormonal therapy, protocol after applying of nursing intervention designing protocol **Conclusion:** There were improvement regarding patients` knowledge, and adherence level after applying nursing intervention protocol. **Recommendations:** Nurses should counsel cancer patients about oral hormonal therapy, addressing the reasons for non-adherence and handling them.

**Keywords:** Adherence, Breast cancer, Knowledge, Oral hormonal therapy & Women.

### Introduction

For individuals who test positive for hormone receptors, oral hormonal therapy is a crucial component of breast cancer treatment. It is advised to take adjuvant hormonal treatment every day for five to ten years. Adjuvant hormonal therapy lowers the risk of recurrence and death in patients who test positive for hormones (Bui, et al., 2020).

Progesterone and Estrogen are transported through the bloodstream. They adhere to hormone receptor proteins on the surface of breast cancer cells when they come into contact with them. The cancer cell is prompted to expand by this link, which functions as an "on switch." Hormone treatment aims to stop hormones from binding to cancer cells, depriving them of the energy source necessary for growth. (Okamoto, et al., 2021).

Breast cancer is quite prevalent and causes a significant burden in all nations. Let's say a patient with cancer conforms to his doctor's prescription schedule and follows the treatment plan. Oral hormone treatment raises the chance of survival while lowering the risk of recurrence. To effectively

accomplish both short- and long-term benefits, patients must be satisfied with their therapy, which in turn will motivate them to take their meds as prescribed. Treatment satisfaction assessments, on the other hand, assist medical practitioners in precisely determining how satisfied a patient is with a certain medication so that they may either alter the treatment plan or come up with an alternative. (Koni, et al., 2023).

When it comes to the education and symptom management of patients receiving oral hormonal treatment, nurses have always been essential. The assistance of the oncology nurse will now be essential to the efficient care of these patients since more and more patients are self-administering oral hormonal medication at home. (Sefonias, et al., 2022).

It is common for patients to refer to it as the "cancer pill" and believe it would work similarly to taking a vitamin or over-the-counter pain reliever. Oncology nurses get familiar with patients taking oral hormonal treatment because, even though the side-effect profiles of many oral hormonal therapy medications are quite favorable, major systemic adverse effects

can still occur. This makes early detection and fast management crucial. (Sefonias, et al., 2022).

The creation of training programs that guarantee patients comprehend the administration of medications, possible adverse effects, and self-care techniques must be the main priority. The proactive role that nurses need to take in treating patients who are taking oral hormonal medication on their own. Adherence to oral hormonal medication may be significantly increased by using a trained nurse approach. (Sefonias, et al., 2022).

### Significance of the study:

According to South Egypt Cancer Institute, Assiut University Hospitals, the number of patients in 2021 was (500). Also, from researcher experience, was noticed that most women with breast cancer are not committed to taking oral hormonal therapy, and patients need to be more knowledgeable about their treatment. So, this study is the first research protocol at the South Egypt Cancer Institute to provide nursing intervention protocol for Improving knowledge and adherence of women with breast cancer regarding oral hormonal therapy.

### Aim of the study:

General aim:

To evaluate the Effectiveness of nursing intervention designing protocol in Improving knowledge and adherence among women with breast cancer regarding oral hormonal therapy

Specific objectives:

1. Assess knowledge among women with breast cancer regarding oral hormonal therapy.
2. Assess the level of adherence among women with breast cancer receiving oral hormonal therapy.
3. Evaluate the effectiveness of nursing intervention designing protocol in improving knowledge and adherence of women with breast cancer regarding oral hormonal therapy.

### Research Hypotheses:

- H1.** Knowledge of women with breast cancer will be improving after the applying of nursing intervention designing protocol regarding oral hormonal therapy.
- H2.** Level of adherence among women with breast cancer receiving oral hormonal therapy will be improve after applying nursing intervention designing protocol

### Research design:

Quasi-experimental research (pre-post) was utilized to conduct the study.

### Setting:

This study was conducted in the medical oncology department and outpatient clinic at South Egypt Cancer Institute, Assiut University Hospitals, this

sitting is specialized in treatment of only cancer patients.

### Sample size:

A total convenient number of 200 adult women with a diagnosis of metastatic breast cancer were included in this study, their ages ranged from (18 to 65) years, new receiving oral hormonal therapy (Aromatase inhibitors) (Letrozeole, Anaptazole and Aromasine), free from any chronic illness. As stated by Thompson and Steven (2012). N is the total number of patients (500) receiving oral hormonal treatment for cancer in South Egypt. Steven K. Thompson (2012) states that the following equation was used to pick the 200 patients that made up the sample.

$$n = \frac{N \times p(1-p)}{[N - 1 \times (d^2 + z^2)] + p(1-p)}$$

Total patient population size of 500 attended the oncology unit. During year 2021-2022

Z= confidence levels is 0.95 and is equal to 1.96

D= The error ratio is=0.05

P=The property availability ratio and neutral=0.50.

### Study Tools:

#### Structured Interviewing Questionnaire:

This tool was used to assess demographic data and medical history for breast cancer patients undergoing oral hormonal therapy as well as to assess patients' knowledge and level of adherence to hormonal therapy. This tool was developed by the researcher after reviewing and utilizing the most recent and relevant literature, it consisted of four parts:

**Part I: Demographic data:** Included: patient age, level of education, occupation, marital status, and residence.

**Part II: Medical history and laboratory investigations:** Include the following family history of cancer, duration of illness, type, stage, site of cancer, types, and response to oral hormonal therapy).

**Part III: Knowledge assessment:** Regarding oral hormonal therapy and adherence. (Definition of oral hormonal therapy, aim for oral hormonal therapy, teaching of compliance, causes of noncompliance).

#### Scoring system:

The overall knowledge scores were designed to be one grade for every right response and zero for wrong answers and ignorance. The item scores were totaled and transformed into a percentage for each area of expertise. The patients' knowledge will be rated as follows: fair if 50% -70%, good if >70% and bad if <50%.

#### Part IV: Morisky Medication Adherence Scale (MMAS-8):

The MMAS was created by Morisky et al. (2008) and evaluates questions that address the conditions behind adherence behavior. The researcher used it to gauge

the degree of adherence among patients to their treatment plan. One of the most popular instruments for evaluating patients' adherence is MMAS-8. It is quick and easy to use because it has eight items with yes/no answers.

#### **Contents of (MMAS -8)**

**Item (1):** Inquires about pill-taking fatigue.

**Item (2):** Inquires about causes other than failing to take prescription drugs.

**Item (3):** Inquires about reducing or quitting medicine without notifying a doctor since the patient feels worse after taking it.

**Item (4):** Inquires about forgetting to pack prescription drugs for trips or vacations.

**Item (5):** Inquires about taking medicine the day before.

**Question (6):** Is it possible to quit taking medicine at any time?

**Item (7):** Inquires about having trouble following the prescribed course of action.

**Item (8):** Inquires about having trouble remembering to take all prescribed drugs.

#### **Scoring system:**

- For questions 1, 2, 3, 4, 6, and 7, a score of zero was assigned for a positive response and a score of one for a negative response (Yes= 0, No= 1).
- On the other hand, a positive response on question 5 received a score of one, while a negative response received a score of zero (Yes = 1, No = 0).
- On a five-point Likert scale, item 8 was scored as follows: once in a while/sometimes/usually/always; a score of zero was assigned for Never/Rarely.
- The total score was eight. Patients who had a score below 6 were considered to have low adherence. Patients who had a score between 6 and 8 were considered to have medium adherence. While patients who had a score equal to 8 were considered to have high adherence.

#### **Nursing intervention protocol for breast cancer women undergoing oral hormonal therapy.**

It was developed by a researcher. This tool aimed to improve patients' knowledge and adherence level for this women, Knowledge about hormonal importance of adherence to oral hormonal therapy, time, and methods helps in adherence to oral hormonal therapy.

#### **Procedure for data collection:**

##### **Ethical approval:**

The scientific research ethics committee at Assiut University Faculty of Nursing provided ethical approval for the study before it was carried out, citing code number 1120240501 the ethics committee of the Faculty of Nursing granted permission to conduct the study. To obtain authorization to gather the data required for this study, a formal letter was written and sent to the dean of South Egypt Cancer Institute by the dean of Assiut University's nursing faculty. The

patient's right to decline involvement in the study and their ability to withdraw at any moment were both stressed by the researcher as voluntary aspects of the investigation. Before any patient participated in the current investigation, their verbal agreement was acquired. By encrypting all data, confidentiality, and anonymity of any information gathered were guaranteed.

##### **Procedure:**

The present study proceeded using the following phases:

##### **Preparatory phase:**

The researcher met the selected patients from the inpatient department and outpatient clinic; each patient was informed of the purpose and nature of the study. Baseline data collected knowledge and adherence level.

##### **Content validity:**

Was completed by five medical and nursing staff experts, the instruments' final format was established, and any necessary changes were made.

##### **Content reliability:**

The tools were created in their final form and put through a reliability test utilizing the Cronbach test to gauge internal consistency across the board. The instruments demonstrated their dependability at (0.73, 0.71 and 0.81, respectively).

After outlining the purpose of the investigation, the director of the South Egypt Cancer Institute at Assiut University Hospitals granted formal authorization to carry out the study.

##### **Pilot study:**

A pilot research was carried out with 20 patients, or 10% of the sample, to assess the tools' clarity and feasibility. No modifications done to the tools, so Patients from the study were included.

##### **Implementation phase:**

The researcher provided the nursing intervention regimen to the trial group.

- The material of the nursing intervention regimen was covered in two sessions, lasting around sixty minutes each. The study was carried out during the early shift. Each student received the instruction methodology individually. One of the family members attended the session to make sure the patient received support and to watch over them when they followed the regimen at home.
- Content from the first section of the informative pamphlet was covered in the first session. Introduction (Definition of oral hormonal therapy, aim for oral hormonal therapy, teaching of compliance, causes of noncompliance).
- The second session covered the second portion of the educational booklet (Nursing teaching protocol) by providing them with colored pictures, and videos

and making discussions about barriers to adherence to medications and how to overcome these problems.

- Nursing teaching included information about the side effect of oral hormonal therapy and nursing management (nausea, vomiting, diarrhea, hot flashes, vaginal discharge and dryness, sexual health concerns, weight changes, mood changes, and fatigue. These choices changed in response to information regarding better effectiveness and side effects. Treatment adherence cannot be taken for granted; patients' preferences about the administration of drugs may have an impact. Nursing experts reviewed the information to ensure it was clear, thorough, and applicable. Changes were made as necessary.
- The patients completed feedback after each session to gauge their level of knowledge. The researchers then went over any challenging material.
- To aid in their retention of the knowledge, each patient received a copy of the booklet during the session in understandable Arabic.
- The Nursing intervention protocol was carried out over 2 months for patients.
- The researcher scheduled a follow-up appointment with the patients, which took place in the South Egypt Cancer Institute's outpatient clinics two months later.

- The researcher used social media to create a group and assured that the patients would follow the regimen every two weeks over the phone. Also to evaluate oral hormonal treatment compliance.
- Information gathered between the start of February 2023 and the conclusion of August 2023.

#### Evaluation phase:

Patients were re-evaluated two months later. In order to assess the impact of the teaching regimen, patients attended the follow-up sessions. It lasted around twenty minutes.

#### Statistical analysis

The homogeneity variances and normalcy of the data were assessed using the Anderson-Darling test. Whereas continuous variables were defined by mean and standard deviation (Mean, SD), categorical variables were described by number and percent (N, %). To compare two categorical variables, use the chi-square test and the Fisher exact test; to compare two continuous variables, use the t-test and the ANOVA test. A statistically significant difference was defined as a two-tailed  $p < .05$ . The relationship between the scores was displayed using Person Correlation. IBM SPSS 20.0 was used to analyze the data.

#### Results:

**Table (1): Distribution of studied sample according to demographic data n=200**

Variables	N	%
<b>Age by years :</b>		
30 < 40	18	9
40 < 50	72	36
50 - 60	62	31
60 ≤ 65	48	24
<b>Level of education:</b>		
-Illiterate	112	56
-Read and write	42	21
-Preparatory school	8	4
-Secondary school	32	16
-University	6	3
<b>Occupation:</b>		
Housewife	200	100
<b>Marital Status:</b>		
-Single	4	2
-Married	196	98
<b>Residence:</b>		
-Urban	14	7
-Rural	186	93

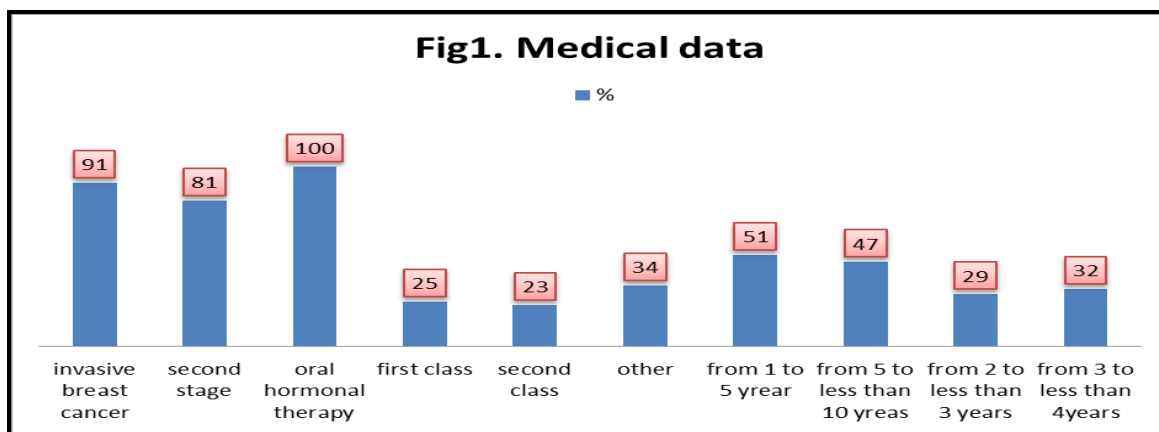


Figure (1): Medical data

Table (2): Total level of knowledge pre /post nursing intervention protocol on adherence of breast cancer women undergoing oral hormonal therapy n=200

Total knowledge 0-12 score	Pre-test		post-test		X2 and sig.
	N	%	N	%	
Poor knowledge < 50	200	100.0	0	0	200.000
Good knowledge > 50	0	0.0	200	100	P=.001

Chi-Square Tests      \*=Significant difference      \*p≤0.05  
 \*\*= highly significance      \*p≤0.01      Ns= Non significant difference      P>0.05

Table (3): Patient’s adherence with oral hormonal therapy pre and post-nursing intervention protocol among breast cancer women undergoing oral hormonal therapy n=200

Medication compliance attributes 0-8 score	Pre		post		X2 and sig.
	N	%	N	%	
Low adherence (> 6)	160	80.0	2	1.0	131.144 P=.001
Medium adherence ( 6 > 8)	40	20.0	172	86.0	
High adherence (8)	0	0.0	26	13.0	

Chi-Square Tests      \*=Significant difference      \*p≤0.05  
 \*\*= highly significance      \*p≤0.01      Ns= Nonsignificant difference      P>0.05

Table (4): Relation between demographic data of patients and medication adherence no=200

Variables	follow-up	Low adherence		Medium adherence		High adherence		Sig .p
		N	%	N	%	N	%	
<b>Age</b>								.001
	30 > 40yrs	Pre	14	7.0	4	2.0	0	
	Post	0	0.0	16	8.0	2	1.0	
40 > 50yrs	Pre	60	30.0	12	6.0	0	0.0	
	Post	2	1.0	62	31.0	8	4.0	
50 > 60 yrs	Pre	50	25.0	12	6.0	0	0.0	
	Post	0	0.0	50	25.0	12	6.0	
60 – 65yrs	Pre	36	18.0	12	6.0	0	0.0	
	Post	0	0.0	44	22.0	4	2.0	
<b>Level of education</b>								
	Illiterate	Pre	96	46.0	20	10.0	0	0.0
	Post	0	0.0	98	49.0	14	7.0	
Read and write	Pre	40	20.0	2	1.0	0	0.0	
	Post	2	1.0	30	15.0	10	5.0	
Preparatory school	Pre	8	4.0	0	0.0	0	0.0	
	Post	0	0.0	8	4.0	0	0.0	
Secondary school	Pre	20	10.0	12	6.0	0	0.0	
	Post	0	0.0	30	15.0	2	1.0	
University	Pre	0	0.0	6	3.0	0	0.0	
	Post	0	0.0	6	3.0	0	0.0	

Variables	follow-up	Low adherence		Medium adherence		High adherence		Sig .p
		N	%	N	%	N	%	
<b>Marital Status</b>								
Single	Pre	2	1.0	2	1.0	0	0.0	.001
	Post	0	0.0	2	1.0	2	1.0	
Married	Pre	158	79.0	38	19.0	0	0.0	
	Post	2	1.0	170	85.0	24	12.0	
<b>Residence</b>								
Urban	pre	0	0.0	14	7.0	0	0.0	.001
	post	0	0.0	14	7.0	0	0.0	
Rural	Pre	160	80.0	40.0	20.0	0	0.0	
	Post	2	1.0	172	86.0	26	13.0	

Chi-Square Tests

\*\*= highly significance

\*=Significant difference

\*p≤0.01

\*p≤0.05

Ns= Non significant difference

P>0.05

**Table (1):** About two-thirds of the studied sample their age more than forty. The majority of them are married, and around half of them are illiterate. Concerning occupation and residence, all of them are housewives, and most of them are from rural areas.

**Figure (1):** Shows that, not all patients get oral hormonal treatment (100%), nor do the majority of patients (91%), have invasive breast cancer. A third of the patients (34%) are classified as fourth class based on their family history. In terms of length of sickness, less than half of the patients (47%) report that their disease has lasted five to ten years. As seen in Figure 1, about one-third (32%) of them had oral hormonal treatment for three to four years.

**Table (2):** This table reveals that; when comparing the pre- and post-implementation nursing intervention protocol on adherence of breast cancer patients receiving oral hormonal treatment, there are a statistically significant difference and improvement.

**Table (3):** This table shows that most of the studied patients > 90% achieved medium to high scores regarding compliance for oral hormonal therapy post-implementation of nursing intervention protocol with high statistical significance for adherence.

**Table (4):** This table shows the statistically significant difference between demographic data and medication adherence pre/post implementation of nursing intervention protocol.

**Discussion:**

According to the current study, the majority of the patients in the analyzed group were between the ages of 40 and 50. Most of them were married, and the majority lacked formal education. In terms of employment and place of residence, the majority of them (93%) were housewives.

This is consistent with research by **Elmaadawy et al. (2022)** titled "Factors Affecting Adherence to Adjuvant Hormonal Therapy Among Women with Breast Cancer," which found that less than half of the women in the study were fifty years of age or older.

Additionally, our findings are consistent with a study by **Lima et al. (2021)** titled "Global Breast Cancer Incidence and Mortality Trends by Region, Age-Groups, and Fertility Patterns," which found that while breast cancer incidence is rising globally, it is most prevalent in women between the ages of 50 and 70. According to researchers, this might be explained by the fact that aging is one of the genetically related variables that causes breast cancer.

Our investigated patients' family histories place them in the second class of family history. Roughly half of the patients had been unwell for five to ten years, and roughly one-third had been receiving oral hormonal treatment for three to four years.

This outcome concurs with the findings of **Abdel Aziz et al. (2022)**. In terms of hormone therapy, two to less than four years was when more than half of the women in the study began receiving it. Additionally, the majority of them take aromatase once daily and the medication orally.

This is in line with a study by **Yussof et al. (2022)** about the factors influencing breast cancer patients' five-year adherence to adjuvant endocrine therapy, which found that receiving the full benefits of hormone treatment requires patients to adhere to their treatment plan for at least five years.

Our findings showed that, following the adoption of a nurse instruction regimen on adherence of women with breast cancer taking oral hormonal treatment, all patients had a slanderous level of knowledge.

This outcome is consistent with **Tan et al.'s (2021)** study, "Beliefs about medicines and adherence in women with breast cancer on adjuvant endocrine therapy," which discovered that most participants' knowledge of hormonal therapy and breast cancer was inadequate. A clear and thorough Arabic brochure that provides details on the action, side effects, and optimal time to take medicine is much needed by women.

Relying on the fact that patient adherence to the prescribed course of action and the medication's

effectiveness are both critical components of treatment efficacy. Very little was published in the literature on the investigation of endocrine therapy compliance for breast cancer in China, despite the fact that there are some studies measuring adherence that compare the data gathered from these various studies. Studies on this topic are therefore crucial because they may point out potential issues and offer solutions for enhancing and promoting drug adherence in China. This finding is consistent with that of **Toivonen et al. (2020)**, who discovered a good association between medication adherence and the overall knowledge, self-efficacy, and social support of women undergoing hormone treatment for breast cancer.

According to our research, there was a statistically significant difference in the adherence of breast cancer patients receiving oral hormonal treatment before and after the nursing intervention protocol was implemented.

More treatment satisfaction was linked to increased adherence to oral cancer medications, including hormonal therapy, according to a prior study by **Koni et al. (2023)** titled "Adherence to oral anticancer hormonal therapy in breast cancer patients and its relationship with treatment satisfaction." Good adherence to oral hormonal therapy was highly correlated with higher levels of treatment satisfaction, particularly concerning side effects.

According to our research, the majority of patients (90%) who were evaluated had compliance levels between medium and high after the nursing intervention protocol was put into place. There was also a significant statistical difference in these scores. This is in line with the findings of a study by **Stahlschmidt et al. (2019)** titled "Adherence and Quality of Life in Women with breast cancer receiving oral hormone therapy," which found that adherence is essential to the effectiveness of hormonal therapy (HT), which has been shown to improve survival rates and lower mortality and recurrence rates.

Given that hormone therapy is a long-term treatment technique, it is also critical to investigate treatment adherence and the associated variables. The majority of women in this research exhibited poor to medium adherence, which was mostly characterized by medication forgetfulness. Due to schedule changes or forgetfulness, the majority of them stated that they either forgot once or twice a year or failed to take medication at the same time every day. Of the women who used tamoxifen for vaginal discharge and dizziness, just one desired to quit taking her medicine. The techniques used in studies to grade and measure adherence differ. According to clinical research, 72-292% of women comply with their treatment plan for

the entire recommended time. These women are, nonetheless, attentively watched after and urged to take their medications as directed. In medical environments, this percentage may be as low as 50%. Our research demonstrates a statistically significant change in medication adherence and demographic information before and after the nurse intervention strategy was put into place.

This finding is consistent with a study by **Lima et al. (2021)** titled "Global Breast Cancer Incidence and Mortality Trends by Region, Age-Groups, and Fertility Patterns," which discovered that while the incidence of breast cancer is rising globally across all age groups, it is highest in women between the ages of 50 and 70. Plans for motivational interviews and educational protocols concerning the benefits of hormone therapy should be made to motivate patients to take their medications as prescribed.

### Conclusion:

There was a statistically significant difference between pre and post-implementation of nursing intervention protocol regarding knowledge & adherence of women with breast cancer undergoing oral hormonal therapy with ( $P=.001^{**}$ ).

### Recommendations:

The present study's findings lead to the following recommendations for further investigation and application:

1. Women with breast cancer should be scheduled for motivational interviewing and educational sessions promoting oral hormonal treatment as a beneficial strategy.
2. Nurses should provide oral hormonal treatment advice to cancer patients, as well as address and manage any non-adherence issues.
3. A detailed and simple Arabic pamphlet that provides information on the action, side effects, and optimal time to take medicine is needed for women.

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### Conflict of interest:

There is no conflict of interest.

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