

Introducing Standardized Nursing Protocol for Breast Cancer Women Receiving Chemotherapy

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Abstract: Background: Assessments of patient satisfaction have become widely accepted as a legitimate and worthwhile approach to improve the service quality. Satisfaction studies are common in areas such as general practice or midwifery, but the approach has hardly been applied to assess care for cancer patients. The healthcare goal is to provide the patient with the best health care and service possible. The service providers are in constant effort to better meet the patients' needs and expectations.

Method: The study used a quasi-experimental research design.

Setting: The study was conducted at the Oncology Center in Mansoura University Hospitals, Mansoura city, Dakahlia Governorate. The study sample was 94 women with breast cancer attending the previously mentioned setting for chemotherapy.

Tools: I- structured interview questionnaire this tool will include three parts: Part one: patient's general characteristics (name, age, marital status, family size, education level, etc.). Part two: patient's obstetric history (e.g., parity, gravidity, abortion). Part three: included the Site of cancer, cancer diagnosed and mastectomy. Part four: chemotherapy information includes interval between sessions, number of sessions, type of chemotherapy and dose of chemotherapy. II: EORTC IN – PATSAT32 for patient satisfaction. III: Follow-up card: included the schedule of appointments for chemotherapy during the study period.

Results: showed strong statistically significant difference between studied groups regarding patients' satisfaction within ($P < 0.001^{**}$).

Recommendation, study recommended introducing standardized nursing protocol for breast cancer women receiving chemotherapy for better satisfaction.

Key words: protocol, cancer, chemotherapy.

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I. Introduction

Breast cancer is the most common cancer in women worldwide. Early breast cancer diagnosis and improvement of therapeutic procedures have reduced the impact of treatment on function and increased the proportion of possibly employed survivors¹. Improvements in breast cancer treatment and early detection have resulted in a decrease in the mortality rates of patients with breast cancer in the last decades. Among patients with early-stage breast cancer, the use of adjuvant chemotherapy has had a dramatic effect decreasing the risk of recurrence and improving survival rates². Most patients with breast cancer start adjuvant chemotherapy within 30 to 40 days of surgery. It is thought that chemotherapy administration delayed beyond this time can decrease the benefit provided by cytotoxic systemic therapies³. Chemotherapy-induced side-effects are common in breast and gynecologic cancer and significantly impact their quality of life. Supportive therapies for prevention and treatment of side-effects are an integral part of oncology today⁴. They are included in current guidelines and treatment protocols and mainly focus on the prevention and/or treatment of potentially life-threatening organ toxicities (e.g., myelotoxicity, anemia, renal, and hepatic function) or severe vomiting which might not allow the application or continuation of chemotherapy⁵. The delivery of cancer care must be ensuring the best outcomes and experience for the patient by drawing on the wide range of skills of the multidisciplinary team. These are a combination of technical and clinical skills, together with good communication, empathy and involving the patient in all aspects of care planning and delivery⁶.

II. The study Aim

The aim of the study was to introduce standardized nursing protocol for breast cancer women receiving chemotherapy.

III. Subjects &method

3.1 - Research Design: A quasi-experimental research design was used in this study.

3.2 - Setting: This study conducted at the Oncology Center in Mansoura University Hospitals, Mansoura city, Dakahlia Governorate.

3.3 Participants: A purposive sample of 94 women with breast cancer attending the Oncology Center for chemotherapy were eligible to be enrolled in this research when they fulfill the following **inclusion criteria:**

- Eighteen years old or more.
- Free from severe chronic illness requiring special care.
- Not suffering from other cancer except breast.

3.4 Tools: Three tools used for data collection.

3.4.1-Tool I: Structured interview questionnaire which include three parts:

It was developed by the researcher to include four parts.

Part 1: concerns with the patient's general characteristics (e.g., name, age, marital status, family size, education level, occupation, and health insurance).

Part 2: concerns with the patient's obstetric history (e.g., parity, gravidity, abortion).

Part 3: includes the Site of Cancer, Cancer diagnosed and Mastectomy.

Part 4: includes chemotherapy information interval between sessions, number of sessions, type of chemotherapy and dose of chemotherapy.

3.4.2-Tool II: EORTC IN – PATSAT32 for patient satisfaction

This tool used to assess the patient's satisfaction about the Oncology-relevant aspects of care provided, health care providers; including Oncologists and nurses, and the organization. This questionnaire aimed to highlight aspects of care needing improvement in the oncology setting. It consists of 31 items developed by **offFayers et al., (2001)**; 11 items to rate the Oncologist, 11 items to rate the nurses, 9 items to rate the services and organization, and on more question to rate the general care given during the hospital stay. Each item is to be evaluated on a 5-point Likert scale (poor, fair, good, very good, and excellent), with the higher score indicating a higher satisfaction.

3.4.3-Tool III: Follow-up card

This card included the schedule of appointments for chemotherapy during the study period. In this card the researcher has to check the patient's attendance or no.

Pilot study

A Pilot study was done on 10 % of the study sample. The pilot was done to evaluate the relevance, clarity and content validity of the tools used for data collection, evaluate time needed for the participants to complete study tools and to find out possible obstacles that might face the researcher and interfere with data collection. The pilot sample was excluded from the analyzed study sample. This phase consumed about three months.

Field work

- The data collection started from January 2017 till December 2017. It involved the control group and intervention group. Women were attended to the outpatient clinic; Oncology Center at Mansoura University Hospital to receive chemotherapy which was range from minimum 6 cycles to maximum 16 cycles; a period of rest between 15 days or 21 days between each cycle is maintained.
- The researcher gathered data from the control group from the period of 15/1/2017 till 28/05/2017, and from the period of 29/5/2017 till 21/12/2017 data was collected from the intervention group.
- After obtaining official permission to perform the study, throughout the first cycle of chemotherapy the researcher met each participant that fulfill the inclusion criteria at outpatient clinic on days of medical oncology (Sunday, Monday, Wednesday and Thursday) and introduced herself, explained her mission and told the participants that her role is to help them and gained the informed consent from each participant to carry out the study.
- The researcher offered booklet to each participant in the intervention group, which included information about chemotherapy, adverse effects of chemotherapy and how to manage these side effects.
- The intervention group received their chemotherapy according to the developed nursing care protocol. The researcher did the nurse role during providing the chemotherapy dose. She considered the pre-

administration precautions, provide the care during and after the chemotherapy session, care for the potential side effects that may occur after the chemotherapy and help the patients to get all assistance services like any diagnostic procedures or laboratory investigations.

- The control group received their care under the conventional management approach
- The researcher met each woman individually and the data collection tools filed by the researcher in the last visit from both intervention and control group.

Ethical considerations

- Ethical approval attained from the research ethics committee, Faculty of Nursing at Mansoura University.
- Official permission to carry out the study attained from the responsible administration of the hospitals.
- Written consents obtained from breast cancer woman after explaining the purpose of the study. Each woman had the right to withdraw from the study at any time.
- Privacy and confidentiality of the collected data assured.

Statistical analysis

Data were analyzed with SPSS version 21. The normality of data was first tested with one-sample Kolmogorov-Smirnov test.

Qualitative data were described using number and percent. Association between categorical variables was tested using Chi-square test.

Continuous variables were presented as mean ± SD(standard deviation) for parametric data. The two groups were compared with Student t test while ANOVA test was used to compare more than 2 means. Pearson correlation was used to correlate continuous data.

IV. Results

Table (5.1): shows distribution of the studied groups regarding to general characteristics. It reveals that more than half (51.1% & 68.1% respectively) of the studied women aged more than (50) years old. Near to two third (63.8% & 68.1% respectively) of the studied women were living in rural areas. The majority of the women (70.2% & 80.9%) were married. Nearly three fourth of the women (89.4% & 74.5% respectively) were housewives. There were no statistically significant differences between the studied groups (p>0.005).

Table (5.1):Comparison between Intervention and control groups regarding demographic data

Demographic data	Intervention group (n=47)		Control group (n=47)		χ^2	p-value
	No	%	No	%		
Age in years						
20 -	3	6.4	5	10.6	4.97	0.083
40-	20	42.6	10	21.3		
> 50	24	51.1	32	68.1		
Residence						
Rural	42	89.4	35	74.5	3.51	0.061
Urban	5	10.6	12	25.5		
Marital status						
Single	0	0	2	4.3	4.68	0.096
Married	33	70.2	38	80.9		
Widow	14	29.8	7	14.9		
Educational level						
Reading and write	30	63.8	25	53.2	4.98	0.083
Secondary school	16	34.0	15	31.9		
Highly educated	1	2.1	7	14.9		
Occupation						
No working	37	78.7	36	76.6	0.061	0.804
Working	10	21.3	11	23.4		

*significant p <0.05,**highly significant p <0.001

Table (5.2): represent the Comparison between Intervention and control groups regarding patient's follow up card which reveal that near three quarter (70%) of intervention group their duration of chemotherapy were less than 5 months and only near one third (29.8%) in control group with strong statistically significant differences between the studied groups (p<0.005). also, this table shows that there is a strong statistically significant differences between the studied groups (p<0.005) in the attending the chemotherapy sessions.

Table (5.2): Comparison between Intervention and control groups regarding patient's follow up card

	Intervention group (n=47)		Control group (n=47)		χ^2	p-value
	No	%	No	%		
Duration of chemotherapy						
<5 months	33	70.2	14	29.8	15.36	<0.001**
>5 months	14	29.8	33	70.2		
Duration of chemotherapy Mean \pm SD	4.70 \pm 1.45		5.75 \pm 2.17		t=2.75	0.007*
Attendance total of month Median (Min-Max)	6.00 (6.00- 17.00)		8.00 (6.00- 16.00)		Z=3.25	0.002*
Not attendance Median (Min-Max)	0.00 (0.00- 0.00)		2.00 (0.00- 4.00)		Z=6.45	<0.001**

Figure (1): Comparison between Intervention and control groups regarding patient satisfaction

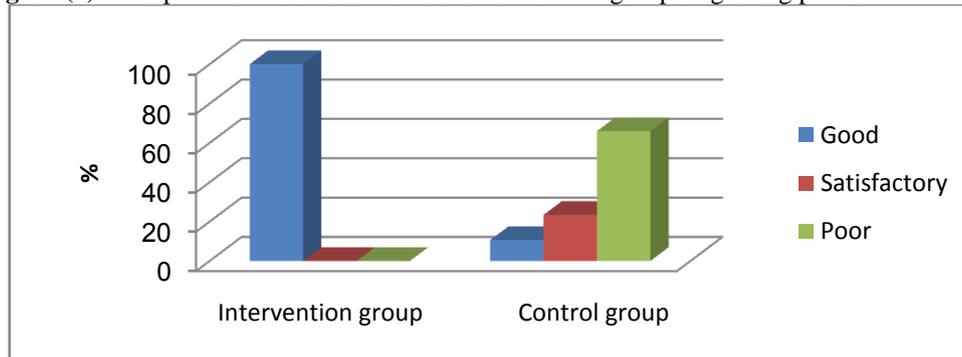


Figure (2): Satisfaction score about doctors

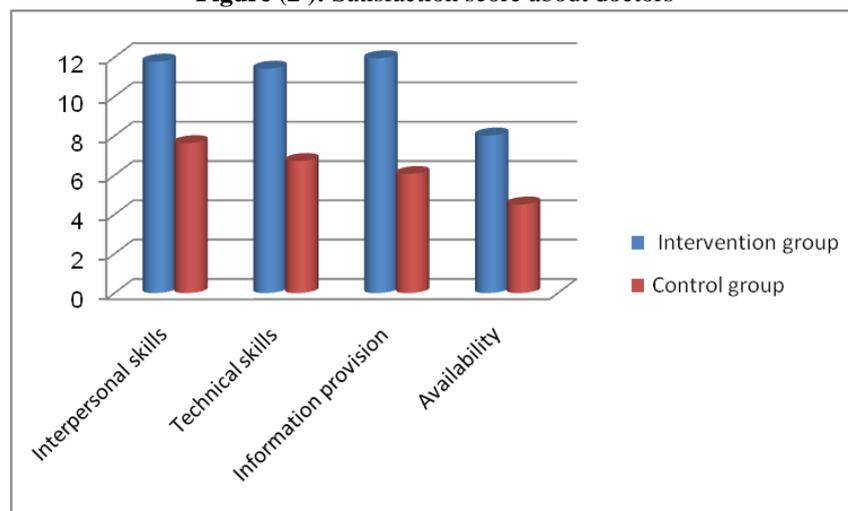


Figure (3): Satisfaction score about Nurses

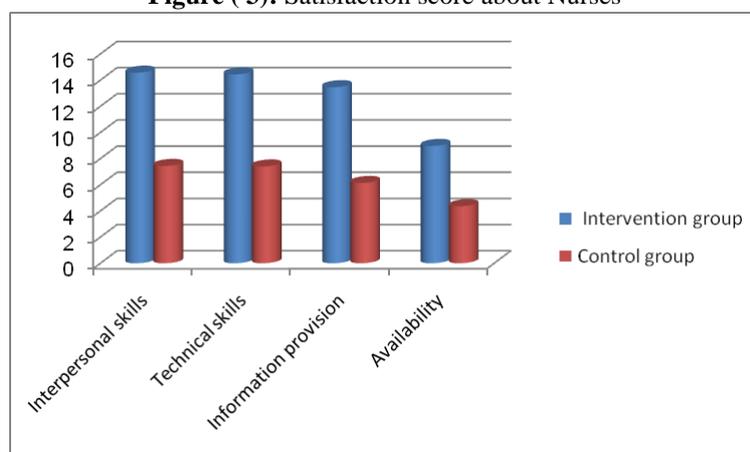


Figure (4): Satisfaction score about score about information exchange, others, hospital staff , waiting time, hospital access, hospital comfort and overall about hospital.

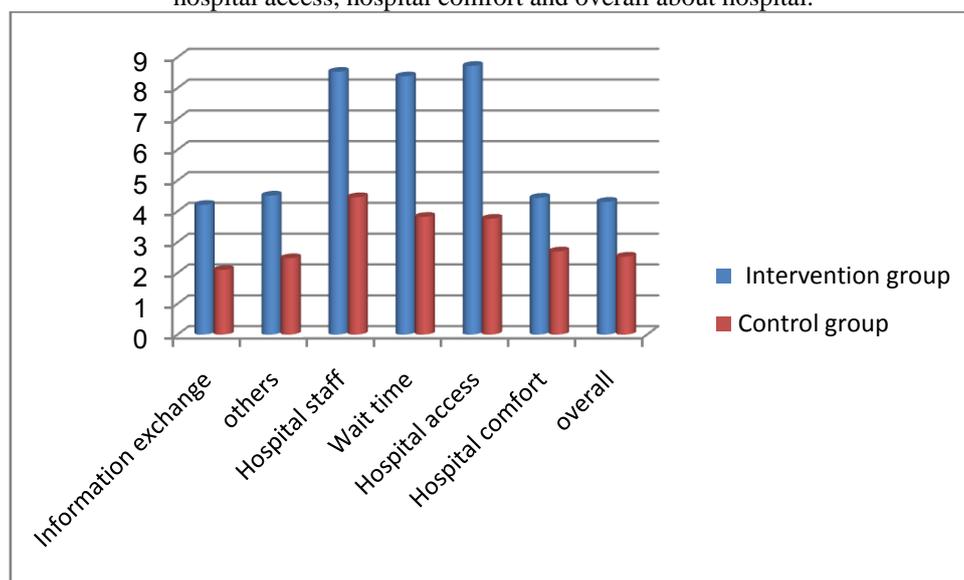


Table (5.3): represent relation between satisfaction score and demographic data which shows that satisfaction score increases in rural area than urban area between intervention group which increase in urban area than rural area in control group with statistically significant difference. Satisfaction score increase in married women than widow between intervention group with statistically significant difference. This table also reveal that satisfaction score increase between working women than not working between control group with strong statistically significant difference

Table (5.3): Relation between satisfaction score and demographic data

	Intervention group (n=47)		Control group (n=47)	
	Mean ± SD	Test of sig. p- value	Mean ± SD	Test of sig. p- value
Age in years				
20 -	125.67±0.57	F=2.688 P=0.079	82.20±8.55	F=1.406 P=0.256
40-	141.00±14.41		60.10±26.99	
> 50	136.62±8.37		74.40±29.13	
Residence				
Rural	139.07±11.67	t=2.289 P=0.027*	84.35±25.96	t=2.772 P=0.008*
Urban	127.00±0.00		63.18±25.82	
Marital status				
Single	-	t=2.32 P=0.025*	63.00±38.18	F=0.611 P=0.547
Married	140.24±12.20		70.81±29.29	
Widow	132.00±7.87		82.28±13.67	
Educational level				
reading and write	138.37±12.22	F=0.465 P=0.631	65.64±31.20	F=1.759 P=0.184
secondary school	137.38±10.88		84.22±18.60	
highly educated	127.00±0		76.46±23.35	
Occupation				
no working	138.73±12.22	t=1.069 P=0.291	64.72±26.69	t=3.802 P=<0.001**
Working	134.30±8.88		96.63±13.32	

Table (5.4): shows correlation between Satisfaction score and duration of chemotherapy. It reveals that there is negative linear correlation between the Satisfaction score and duration of chemotherapy.

Table (5.4): Correlation between Satisfaction score and other parameters

	Satisfaction score			
	Intervention group (n=47)		Control group (n=47)	
	R	P	R	P
Duration of chemotherapy	-0.413	0.004*	-0.055	0.713
Attendance total of month	-0.396	0.006*	0.095	0.525
Not attendance	-	-	-0.283	0.054

V. Discussion

Breast cancer is the most common malignancy in women in the United States and is second only to lung cancer as a cause of cancer death⁷. The development of outpatient chemotherapy has increased the working population of patients undergoing cancer therapy. However, a significant number of cancer survivors experience physical, psychological, and social problems⁸.

Ortiz, 2015 and Van Bekkum et al., 2015 discussed the use of palliative chemotherapy as an additional resource for advanced breast cancer control. However, unnecessary use of chemotherapy may worsen the clinical picture of women, due to the undesirable toxicities and adverse reactions related to this kind of treatment. The nurse is the professional directly dealing with women and their families, being responsible for the administration of the chemotherapeutic agents. Nursing consultation is an effective strategy on an outpatient basis, as it favors the cultivation of a supportive interpersonal relationship, in which management of nursing care implies recognizing and meeting the needs of both patients and families^{9,10}.

In the current study, as a baseline for introducing standardized nursing protocol for breast cancer women receiving chemotherapy, no significant differences were elicited in both groups (the study and control groups). There were no statistically significant differences between the studied groups ($p > 0.005$). This is in line with the study done by Lam, Kwok & Lee in their study about Prevalence and sociodemographic correlates of routine breast cancer screening practices among migrant-Australian women¹¹.

In a new study by Lai et al., 2018¹² it was discussed that the common reasons for utilizing health services were infections and fevers, skin problems, digestive system problems, and mouth/teeth/throat problems. There were no differences in health service utilizations between the nurse-led and routine care groups for subjects receiving four-cycle chemotherapy. For those receiving six-cycle chemotherapy, the estimated number of emergency department visits was 2.188 times (95% Confidence Interval, 1.051 to 4.554) higher for the routine care group when compared with the nurse-led care group ($p = .038$).

Furthermore, on studying the cancer history it was found that all its items were fully significant. It included site of cancer, time of cancer diagnosis and mastectomy. By first analysis of the site of breast cancer it was detected that one sided breast cancer was more common and have had the higher proportion within 70.2% in the intervention group and 91.5% in the control one ($P = 0.009^*$).

According to time of cancer diagnosis; about one third (29.8%) in the control group and about 46.8% in the intervention group were diagnosed with breast cancer in less than three months. On analyzing it was significant with ($P = 0.024^*$). The majority of the women had mastectomy in one side with statistically significant differences between the studied groups ($P = 0.003^*$) as 70.2% was the proportion of the intervention group and 85.1% was the proportion of the control group.

By analyzing the results after applying the standardized nursing protocol with the induction of chemotherapy, a strong significance between the two studied groups was clarified regarding the chemotherapy information which includes Number of sessions and type of chemotherapy, but no significance was found in the dose of chemotherapy.

Regarding the number of sessions, 6-10 sessions was the greater in proportions, as 89.4% was for the intervention group and 61.7% was for the control group within a significant value ($P < 0.001^{**}$). By the type of chemotherapy, adjuvant therapy was the greater in proportions, as 72.3% was for the intervention group and 66.0% was for the control group within a significant value ($P < 0.001^{**}$).

Brett et al., 2018 in a study titled Adjuvant endocrine therapy after breast cancer: a qualitative study of factors associated with adherence, proved that adjuvant chemotherapy has had some factors associated with adherence and non-adherence. Factors associated with adherence were as follows: managing side effects including information and advice on side effects and taking control of side effects, supportive relationships, and personal influences. Factors associated with non-adherence were as follows: burden of side effects, feeling unsupported, concerns about long-term AET use, regaining normality, including valuing the quality of life over length of life, and risk perception¹³.

Comparing the intervention and control groups regarding patient's follow up card including duration of chemotherapy and attendance total of month, it was revealed that near three quarter (70%) of intervention group their duration of chemotherapy were less than 5 months and only near one third (29.8%) in control group with strong statistically significant differences between the studied groups ($P < 0.001^{**}$). Also, it was showed that there was a strong statistically significant differences between the two groups in the attendance of the chemotherapy sessions ($P = 0.002^*$).

This was on line with a study done on 2011, which concluded significant benefits in overall survival and progression-free survival with longer duration regimens of chemotherapy compared with shorter duration regimens in patients with metastatic breast cancer¹⁴.

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A study by Atisha et al., 2015¹⁵ studied the relation between socioeconomic factors and satisfaction with breast cancer procedures showed that satisfaction score increased in rural area than urban area. This was almost like result gained in this study as ($P = 0.027^*$) in the intervention group and was ($P = 0.008^*$) in the control group while testing residence place. Satisfaction score also increased in married women than widow between intervention group with statistically significant difference ($P = 0.025^*$) in the intervention group and was ($P = 0.547$) in the control one according to the marital status.

It was also revealed that this satisfaction score increased between working women than not working between control groups with strong statistically significant difference as ($P < 0.001^{**}$) in the control group and ($P = 0.291$) in the intervention group on according to the occupation. On the other hand, there was no statistically significant difference between the two groups according to age in years and educational level. By testing the relation between satisfaction score and the age ($P = 0.079$) in the intervention group and ($P = 0.256$) in the control one. By testing the relation between the statistical score and educational level it was found that ($P = 0.631$) in the intervention group and ($P = 0.184$) in the control group.

As a result of detecting the relation between satisfaction score and cancer history including site of cancer, cancer diagnosed and mastectomy, it was found that the satisfaction score increased between women whom have cancer in one breast, it was clarified through ($P < 0.001^{**}$). It also increased among women diagnosed from three to six months and having mastectomy in one side among intervention group with strong statistically significant difference ($P < 0.001^{**}$) for each of them.

Three old studies found that the expectations has been met regarding satisfaction studied by **Brandberg, Malm and Blomqvist, 2000; Contant et al., 2000; Ringberg et al., 1999**^{16,17}. Another one studied the experience of receiving breast reconstruction in women in Taiwan reported a relationship where failure to meet expectations led to disappointment with surgery¹⁸. In contrast a recent one reported no relationship between expectations and satisfaction with surgical outcomes¹⁹.

In our study providing information about chemotherapy and its sessions discriminated in women's satisfaction score. Our test included number of sessions, type of chemotherapy, dose of chemotherapy and duration. The satisfaction score increased between women whom received neo-adjuvant chemotherapy and total duration of chemotherapy less than five months in intervention group with strong statistically significant difference ($P < 0.001^{**}$). Also, it increased between women whom receiving six to ten sessions of chemotherapy and combined therapy in intervention group with statistically significant difference ($P < 0.001^{**}$).

Cancer nurses need to develop effective strategies to help patients and their families with emotional burdens and anxiety before and during chemotherapy, inform patients and their families about expected side-effects, monitor side-effects and toxicities of treatments, and improve patient compliance with treatment²⁰.

VI. Conclusion

The findings of the study concluded that:

- Outcomes of the current research support its hypothesis; breast cancer women receiving chemotherapy according to standardized nursing protocol attained better outcome and quality of health care compared to those under the conventional care.
- The applied standardized nursing protocol had no negative side effects or complications on cases. The completion of it had a great effect on quality of health care and patient's satisfaction.

VII. Recommendations

The study recommended the following:

- Encouraging to use the standardized protocol as one of the significant modalities to improve quality of life, better outcome and patient's satisfaction.
- Providing in-service training programs to health care providers concerning the use of standardized protocol and its benefits.
- Applying this protocol on health care providers with some adaptation.
- Replicating the study on a larger sample for generalizing the findings.

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