Effect of Health Literacy Intervention on Self-Management among Older Women with Breast Cancer Undergoing Chemotherapy: A Randomized Controlled Trial Study

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Abstract

This randomized control trial aimed to evaluate the effect of health literacy intervention on self-management among older women with breast cancer undergoing chemotherapy. The study sample composed of 100 older breast cancer patients undergoing chemotherapy, randomly assigned into two groups. The study group (n=50) received six sessions every two weeks and the control group (n=50) received no intervention. Four tools were used; interview questionnaire, All Aspects of Health Literacy Scale, Patients' Self-Management Knowledge, and Chemotherapy Self-Management Scale. Chi-square test, independent samples t-test, paired t-test, and Pearson correlation were used for data analysis. The study findings showed statistically significant improvements in the study group's health literacy, self-management knowledge, and self-management behaviors compared to the control group (p < .01). Health literacy intervention was effective and could be used to enhance patients' health literacy, self-management knowledge, and self-management behaviors in older women with breast cancer undergoing chemotherapy.

Introduction

Aging population is now a global trend. Older adults aged 65 years or more are expected to rise more than double from 761 million in 2021 to 1.6 billion in 2050 (1). Aging is the major risk factor for breast cancer and the peaks of its incidence between 70 and 84 years of age. Breast

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cancer is still a major health concern among the older adults. In older women, it is the most commonly diagnosed cancer and the leading cause of cancer-related death worldwide (2).

Chemotherapy is a common breast cancer treatment that uses in older adults (3). Unfortunately, the older woman has, generally, more co-morbidity and is more likely to suffer chemotherapy side effects compared with young patients that often leads clinicians to reduce doses, delay schedules, or discontinue treatment prematurely, which negatively affects these patients' survival (4). Those women must engage in effective self-management intervention to control their side effects, reduce their physical and psychological symptoms, and improve medication adherence as well as their daily life activities (5).

Barriers to self-management in patients undergoing chemotherapy include difficulty in information access and lack of knowledge necessary for making health-related decisions and controlling their health (6). Therefore, health literacy is critically important in these situations. Health literacy is "the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others" (7)

Low health literacy in cancer patients is associated with poor health-related outcomes, such as increased hospitalization, increased use of emergency services, prolonged recovery, and complications (8). Health literacy is considered key in bridging the gap between cancer patient's needs and the ability of health professionals to meet those needs. Health literacy intervention affects knowledge, attitudes, and behaviors to manage both the physical and psychosocial aspects of cancer and chemotherapy treatment (9). Therefore, this study aimed to evaluate the effect of health literacy intervention on self-management among older women with breast cancer undergoing chemotherapy.

Methods

Study Design and Setting

This randomized control trial study was conducted in the oncology day clinic (an outpatient clinic specified to provide chemotherapy treatment to cancer patients) at Zagazig University Hospitals, in Egypt.

Sample

The sample of this study included 100 older women (50 patients in study group &50 patients in control group) with breast cancer undergoing chemotherapy who fulfilled the following criteria; agree to participate in the study, able to communicate, and independent. We excluded stage four breast cancer patients. The enrolled patients were randomly allocated in a 1:1 ratio to the study

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or control group. Study group received the health literacy intervention while the control group received only routine hospital care.

Sample size calculation

EPI Info software program version 6.04 was used to calculate the sample size. According to hospital records; the total population of older women with breast cancer undergoing chemotherapy is 600 through the year and based on the percent of improvement in a previous study which was 30%(10) with a power of 80% and at confidence level 95%, therefore the sample was 100 patients (50 patients in study group &50 patients in control group).

Tool of data collection

Four tools were used for collection of data. **Tool I:** an interview questionnaire to assess older women' characteristics which included age, residence, marital status, educational level, monthly income, living condition, stage at diagnosis, and number of chemotherapy cycles.

Tool II: All Aspects of Health Literacy Scale (AAHLS) (11):

The AAHLS is a validated questionnaire consisted of 13 questions. This scale based on foundational health literacy designed by Nutbeam to test different skills of health literacy. Patients must choose from three options 'Rarely, Sometimes or often' for eleven questions, with scores ranging from 1 to 3 points, depending on whether the question has positive or negative intent. Two questions are 'Yes/No' answers with a score of 1 for 'Yes' and 3 for 'No'. The total AAHLS score is obtained by the sum of 13 questions ranging from 13-39. Higher scores indicate a higher level of health literacy. Based on expert opinion; a score of 13-26 indicates "inadequate" health literacy and a score of > 26-39 indicates "adequate" health literacy. In the current study, it's Cronbach α was 0.830.

Tool III: Patients' self-management knowledge regarding chemotherapy and its management:

It was developed by the researcher based on reviewing related literatures. It included questions about purpose of chemotherapy, safely handling fluids and waste after chemotherapy, physical activity, and side effects management. The total number of questions is fourteen; every question has 4-5 correct answers. Items were scored one for the correct answer and zero for don't know. The knowledge scores depended on the number of grades the participant obtained regarding all questions. The total grade was computed out of sixty-six (66) grades and knowledge was considered satisfactory if the percent score was 60% or more (> 39.5 grade) and unsatisfactory if less than 60% (< 39.5 grade).

Tool IV: Chemotherapy Self-Management Scale

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It was adapted from the oral chemotherapy self-management scale (12) and was translated and modified by the researcher. It consisted of five dimensions that included: daily life management (6 items), symptom management (6 items), medication management (8 items), emotional cognitive management (7 items), and social support (4 items). The patient responded to each item using a four-point ordinal rating scale (1 = not relevant, 2 = weak relevant, 3 = strong relevant, 4 = very relevant). The sum of the 31-item scores provides the Chemotherapy self-management scale total score ranging from 31 to 124. A score of <75 indicates poor self-management behaviors. A score of ≥ 75 indicates good self-management behaviors.

Data Collection Process

The study was conducted in a separate room at the oncology day clinic at Zagazig University Hospital from June 2022 up to the end of March 2023. The data of the study were collected by the researchers by face-to-face interviews with the patients before and after the intervention. The researcher read and explained each item of the study tools to the older woman and then recorded her response to each item. Data collection took about 25-30 min to complete for each patient. The posttest was done after one month of completing the intervention.

The Health Literacy Intervention

The intervention was designed based on the identified needs obtained from the analysis of the baseline assessment and in view of the relevant literature [(10), (13)]. The intervention was implemented in the form of six sessions (four theoretical and two practical) every two weeks for 30-45 minutes. The theoretical part of the intervention was prepared in the form of an illustrative booklet distributed to all patients in the study group. The practical sessions were prepared in the form of videos and pictures that demonstrate the exercises. The sessions were introduced individually as well as in small groups (2 to 3 patients in each group) according to patient flow. All patients were instructed to perform arm exercises and lower limb exercises by themselves in their homes three times daily.

The Health Literacy Intervention consisted of six sessions as follows:

Session 1: The main objective of this session was to improve older women's knowledge about purpose of chemotherapy, management of blood, and GIT-related side effects of chemotherapy.

Session 2: The main objective of this session was to enhance older women's knowledge about management of neurological, urological, and general side effects of chemotherapy.

Session 3: The main objective of this session was to enhance older women's knowledge about safely handling fluids and waste after chemotherapy, healthy food during chemotherapy, and safety management of medications.

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Session 4: The main objective of this session was to promote older women's knowledge about the management of most psychological problems.

Session 5: The main objective of this session was to promote older women's knowledge regarding health literacy concept, its domains, and ways of its improvement.

Session 6: The main objective of this session was to help the older women apply arm exercises and lower limb exercises.

Ethical Considerations

This research took the ethical approval of the Research Ethics Committee (REC) and the Postgraduate Committee of the Faculty of Nursing at Zagazig University, Egypt. Verbal consent was taken from each patient after a full explanation of the study aim. Patients were allowed to refuse participation, and they were notified that they could withdraw at any stage of the data collection interviews. They were also assured that the information would be confidential and used for research purposes only. The researcher maintains the anonymity and confidentiality of the subjects' data.

Statistical analysis

Statistical analysis was done using the SPSS 22 statistical software package. The descriptive analyses were expressed as frequencies, percentages, means, and standard deviations (SDs). Percentages of categorical variables were compared using the Chi-square test. Independent t-test was used to compare the means of the study variables between the study and control groups, and paired t-test was used to compare the means of the study variables pre and post-intervention in each group. In order to identify the correlation between the main study variables, Pearson's correlation coefficient was used. Statistical significance was considered at p. value < 0.05. Cronbach alpha coefficient was measured to identify the reliability of the scales through their internal consistency.

Results

Older women' characteristics in the intervention and control groups

Table 1 indicates that the mean age of the study and control groups was 64.34 (SD= 5.57) years & 64.16 (SD= 3.28) years respectively. Regarding residence and marital status, 70% of the study group and 80% of the control group belonged to rural areas, 64% of the study group and 58% of the control group were married. In terms of education and monthly income, 60% of the study group and 58% of the control group can't read and write, 66% of the study group and 64% of the control group had insufficient income. Also, 60% of the study group and 62% of the control group lived with their spouse. There were no significant differences in terms of

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demographic characteristics between the study and control groups. The majority of patients in the study and control groups had stage three breast cancer (80% & 88%) respectively, finally; 36% of the study group received more than 6 chemotherapy cycles compared to 42% of the control group and those results were found to be statistically significant (p<0.05).

Effects of the Health Literacy Intervention on Patient's Self-Management Knowledge and Self-Management Behaviors

Figure 2 reveals that there were no significant differences in terms of patient's self-management knowledge between the two groups in the pretest. Meanwhile post-intervention, the study group reported an improvement in the percentage of satisfactory self-management knowledge from 26% to 78% and this improvement was statistically significant (p<0.01). Meanwhile, the control group had no statistically significant difference in self-management knowledge.

Table 2 reveals that there were no significant differences in terms of patients' health literacy and self-management behaviors between the two groups in the pretest. This indicates the homogeneity of both groups at baseline. Table 2 also, reveals that the study group post-intervention reported improvement in the mean scores of total health literacy from 20.18 (SD =5.89) to 26.63 (SD =6.01) and this improvement was highly statistically significant (p<0.01). Meanwhile, the control group showed no statistically significant difference regarding health literacy pre and post-intervention.

In terms of self-management behaviors, Table 2 reveals that there was marked improvement in all domains of self-management behaviors post-intervention only in the study group and this improvement was obvious, especially in daily life management, symptoms management, and emotional cognitive management and this result was found highly statistically significant (p<0.01). Meanwhile, the control group after the intervention reported no statistically significant difference in all domains of self-management behavior.

Correlations between total health literacy, self-management knowledge, and self-management behaviors post-intervention in the study group

According to Table 3, the study results indicated that there was a significant positive correlation between health literacy and self-management knowledge (r =0.612), and self-management behaviors (r =0.499). Moreover, self-management knowledge was positively correlated to self-management behaviors (r =0.267).

Predictors of self-management knowledge, and self-management behaviors post-intervention in the study group

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Table 4 describes that high educational level was statistically significant independent negative predictor of the self-management knowledge score. Meanwhile, urban residence was statistically significant independent positive predictor of the self-management knowledge score. Moreover, Table 5 points to that age and living alone were statistically significant independent negative predictors of self-management behaviors. Conversely, being married and high educational level were statistically significant independent positive predictors of self-management behaviors.

Discussion

The existing study results clarified that the patients in both study and control groups at the pre-test had inadequate health literacy. This might be attributed to the low level of education among most of them plus living in rural areas which are characterized by low medical services and low socioeconomic status that makes access to health information difficult to accomplish. In the same stream, a study conducted in Turkey by ÖZTÜRK & Şenyuva (14) found that the majority of the chemotherapy patients had poor and limited-problematic health literacy levels .

Controversy, a large cross-sectional study conducted in America by Kanu et al. (15) reported that more than three-quarters of the patients had adequate health literacy. Such discrepancy between results might be attributed to differences in educational level, high socioeconomic status, availability of medical services, and easy accessibility of health information from different resources in this country .

After the implementation of the intervention, total health literacy was significantly improved in the study group only compared to the control group who showed no statistical significant difference. This might be attributed to the content of the intervention, which focused on improving communication between patients and their health professionals by encouraging them to ask questions, report their health condition in a straightforward way and also be sure that the health information is obtained from reliable sources. In the same line with the study group results, a study conducted in Iran by Bahrami & Behbahani (16) concluded that the health literacy promotion program can improve the level of health literacy as they found that there were significant changes in the health literacy level immediately after the intervention and 1 month later .

Considering self-management knowledge, the existing study results clarified that more than three-quarters of patients in both groups had unsatisfactory self-management knowledge at pre-test. A possible explanation can be concluded from the study results as the studied patients had low educational levels and poor health literacy resulting in a lack of health information acquisition.

 These findings are consistent with a study conducted in India by Sivakumar & Susila (17) who reported that both the study group and the control group had inadequate knowledge prior to

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chemotherapy cycles and there were no significant differences between the two groups in this regard. Similar results have been emphasized in a study conducted in Palestine by El-Kass et al. (18) who found that more than half of the studied patients had a poor total level of knowledge regarding chemotherapy and side effects management.

Conversely after intervention, more than three-quarters of the study group patients had satisfactory self-management knowledge, while the control group knowledge remained unchanged. This result might be attributed to the effect of the intervention which focused on equipping patients with knowledge about chemotherapy, management of its side effects, diet, and exercises. These findings are consistent with a study conducted in India by Sivakumar & Susila (17) who reported that after the intervention the experimental group had adequate knowledge (95%) on self-care behaviors but, the control group remained having inadequate knowledge.

Pertaining to self-management behavior; the study findings concluded that the patients in the study and control groups had poor self-management behaviors. Such results reflect what the researcher found in other variables; as the patients had poor health literacy and unsatisfactory self-management knowledge which ultimately makes the patients unable to adopt healthy behaviors to control their health. A concordant result was reported by Kim et al. (10) in Korea who found that the mean scores of self-management behaviors before the intervention were 57.12±13.89 & 53.50±17.63 for the experimental and control groups respectively. Moreover, Amin et al. (19) who conducted a study in Egypt highlighted that breast cancer patients show moderate levels of self-care behavior in managing chemotherapy side effects; as the overall self-care practice was 48% .

Meanwhile post-intervention, the study group patients had marked improvement in all domains of self-management behaviors and this improvement was highly statistically significant, especially in daily life management, symptoms management, and emotional cognitive management. Meanwhile, the control group had no statistically significant difference in all domains of self-management behaviors. Such results might be due to the intervention was focused on a healthy lifestyle including diet and exercise as well as educating the patients on how to manage chemotherapy side effects and training them the physical exercises.

 As well, a study conducted in Egypt by Tawfik et al. (5) concluded that after the intervention, the study group showed higher effective self-care behaviors compared to the control group. Another study conducted in Thailand by Tachanan et al. (20) which evaluated the effect of a health literacy enhancement program on self-management among older persons with breast cancer receiving radiation therapy found that the mean self-management scores were significantly higher in patients who received the program than those who received usual care and greater than before receiving the health literacy enhancement program.

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Based on the study findings; health literacy, self-management knowledge, and self-management behaviors showed a significant positive correlation between each other. That is, patients with a higher level of health literacy and self-management knowledge show better self-management behaviors. This might be due to knowledge is the basis and reflection for any behavior and any healthy behavior is often based on correct knowledge. In the same vein, Parker et al. (21) conducted a study in America who found that health literacy mean scores were significantly associated with chemotherapy knowledge.

Moreover, Ahmadzadeh et al. (22) carried out a study in Iran who indicated that there was a positive, meaningful and strong correlation among health literacy and self-care dimensions. Also, Qin et al. (23) who carried out a study in China found that knowledge was independently associated with good practice.

Considering the predictors among study group post-intervention; the study findings exposed that the educational level was associated and a common independent positive predictor for the self-management knowledge and self-management behaviors mean scores. This result might be attributed to the fact that the highly educated patients were more receptive to health education messages and understand the medical instructions given to them. In agreement with this, Amin et al. (19) conducted a study in found that patients who received any level of education showed significantly good levels of self-care compared to illiterate patients.

Based on our study findings, urban residence was a statistically significant independent positive predictor for self-management knowledge. This might be due to the availability of health services and high socioeconomic status that make them more able to access health information.

The study findings revealed also revealed that age was a statistically significant independent negative predictor for total self-management behaviors mean scores. So the more advanced age, the lower the self-management behaviors mean scores. This might be due to the advanced age usually related to many functional, cognitive, and psychological problems that interfere with their ability to control their health. Likewise, AL-Harithy & Wazqar (24) who conducted a study in Saudi Arabia to discover that age was significantly associated with self-management.

Finally, we found that being married was a statistically significant independent positive predictor for total self-management behaviors mean scores. While living alone was a statistically significant independent negative predictor for total self-management behaviors mean scores. This might be due to being supported by a friendly social network making the patients more able to modify their behaviors.

Conclusion

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The study findings revealed that the health literacy intervention resulted in improvement in total health literacy of the study group after the intervention compared to the control group. Also, the majority of the study group had satisfactory self-management knowledge after the intervention meanwhile; the control group remains having unsatisfactory self-management knowledge. Furthermore, the study group patients had marked improvement in all domains of self-management behaviors and this improvement was highly statistically significant, especially in daily life management, symptoms management, and emotional cognitive management. Meanwhile, the control group had no statistically significant difference in all domains of self-management behaviors. The study results also found that health literacy, self-management knowledge, and self-management behaviors showed significant positive correlations between each other. The significant predictors of self-management knowledge improvement were urban residence and high educational level. Meanwhile, age, being married, high educational level, and living alone were significant predictors for self-management behaviors' improvement. According to our study results; health literacy intervention was effective and could be used to improve patients' self-management knowledge and self-management behaviors in older women with breast cancer undergoing chemotherapy.

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Declaration of Conflicting Interests

The Author(s) declare(s) that there is no conflict of interest.

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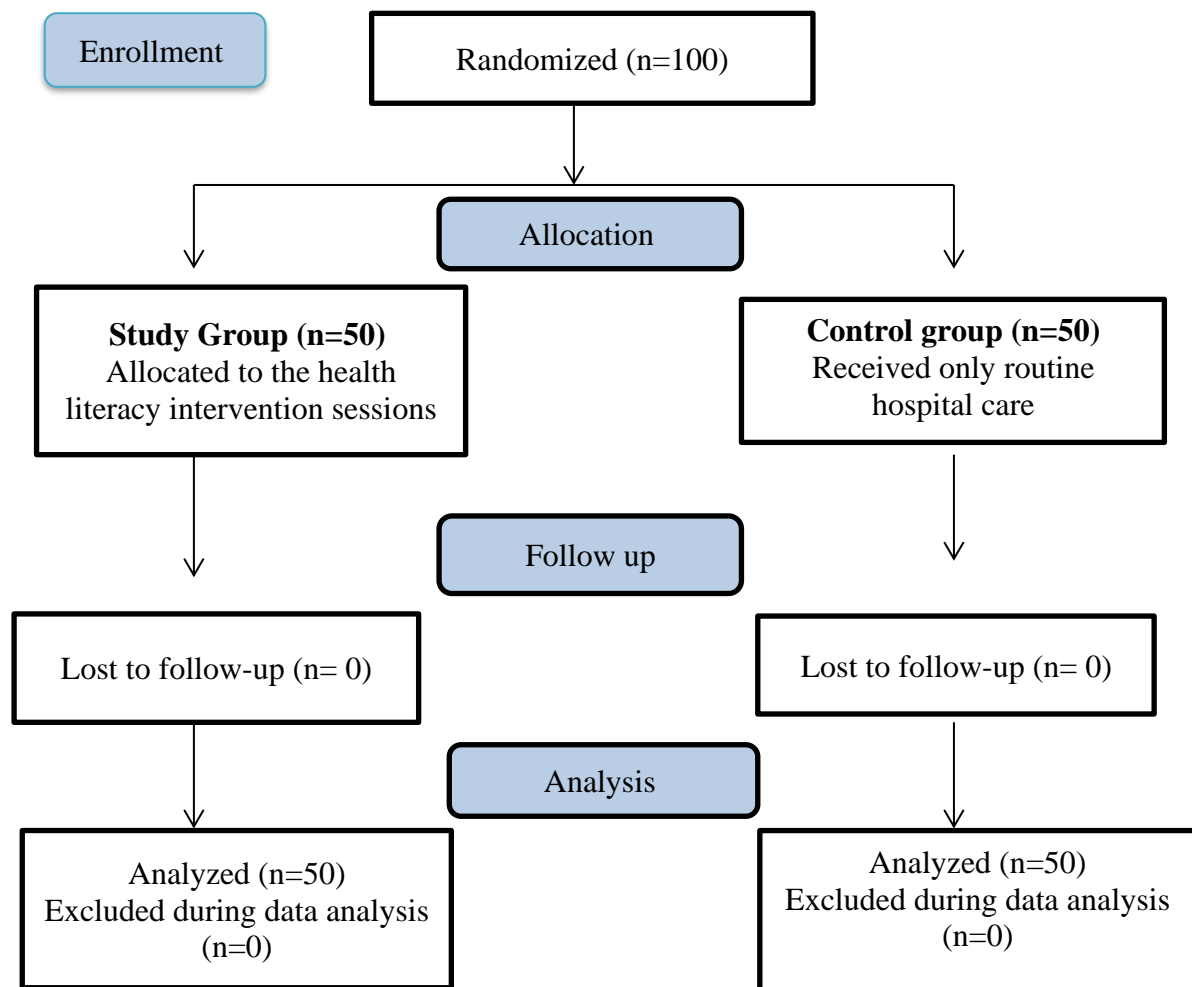
Fig. 1. CONSORT flowchart of the patients throughout the trial

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Table (1): Older women' characteristics in the intervention and control groups (n = 100).

Variables	Study group (n=50)		Control group (n=50)		X^2 test P value
	No	%	No	%	
Age (years)					
60-<70	41	(82.0)	42	(84.0)	1.951
70-<80	9	(18.0)	8	(16.0)	>0.05
Mean± SD	64.34±5.57		64.16±3.28		
Residence					
Rural	35	(70.0)	40	(80.0)	4.253
Urban	15	(30.0)	10	20.0	>0.05
Marital status					
Married	32	(64.0)	29	(58.0)	1.649
Unmarried	18	(36.0)	21	(42.0)	>0.05
Educational level					
Not read and write	30	(60.0)	29	(58.0)	
Read &write	2	(4.0)	2	(4.0)	2.086
Primary education	5	(10.0)	6	(12.0)	>0.05
Secondary education	10	(20.0)	9	(18.0)	
University education	3	(6.0)	4	(8.0)	
Monthly income					
Not sufficient	33	(66.0)	32	(64.0)	1.618
Sufficient	17	(34.0)	18	(36.0)	>0.05
Sufficient and save	0	(0.0)	0	(0.0)	
Living with					

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Alone	5	(10.0)	2	(4.0)	1.704	
Spouse	30	(60.0)	31	(62.0)	>0.05	
Sons /relatives	15	(30.0)	17	(34.0)		
Stage at diagnosis						
Stage I	0	(0.0)	0	(0.0)		
Stage II	6	(12.0)	10	(20.0)	3.866	
Stage III	44	(88.0)	40	(80.0)	<0.05*	
Number of Chemotherapy cycles currently received						
<3	16	(32.0)	8	(16.0)		
3-6	16	(32.0)	21	(42.0)	4.023	
>6	18	(36.0)	21	(42.0)	<0.05*	

χ2 = Chi square test; p < .05 significant.

Table (2): Health literacy and self-management behaviors in the study and control groups
(N=100)

Variables	Group	Pre-test	Post-test	Index scores	Paired t-test	P
		M±SD	M±SD			
Total AAHLS	Study	20.18±5.89	26.63±6.01	13-39	12.701	<0.01**
	Control	20.70±5.22	21.30±5.35		1.503	>0.05
		0.641	11.123			
	^P value	>0.05	<0.01**			
Self-Management Behaviors						
Daily life	Study	11.58±2.25	16.72±1.66	6-24	8.134	<0.01**

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Management	Control	10.81±2.12	10.94±1.35		1.135	>0.05
		1.754	7.505			
	^P value	>0.05	<0.01**			
Symptoms Management	Study	13.25±3.09	22.67±1.52	6-24	8.900	<0.01**
	Control	12.44±3.82	13.38±2.61		1.145	>0.05
		1.690	6.011			
	^P value	>0.05	<0.01**			
Medication management	Study	15.06±4.63	18.59±3.97	8-32	4.671	<0.05*
	Control	15.94±3.29	16.43±4.16		1.503	>0.05
		1.228	3.272	7-28		
	^P value	>0.05	<0.05*			
Emotional cognitive management	Study	17.71±4.98	22.01±2.14		7.845	<0.01**
	Control	17.95±4.12	17.91±3.09		1.135	>0.05
		2.033	7.175			
	^P value	>0.05	<0.01**			
Social support	Study	9.62±2.82	12.29±3.01	4-16	3.701	<0.05*
	Control	10.60±2.79	11.36±2.86		1.079	>0.05
		1.458	1.783			
	^P value	>0.05	>0.05			
Total	Study	67.22±17.77	92.28±12.3	31-124	13.910	<0.01**
	Control	67.74±16.15	70.02±14.07		2.416	>0.05
		1.512	14.612			
	^P value	>0.05	<0.01**			

^ Independent t-test. *Significant at p ‹0.05. **Highly significant at p ‹0.01

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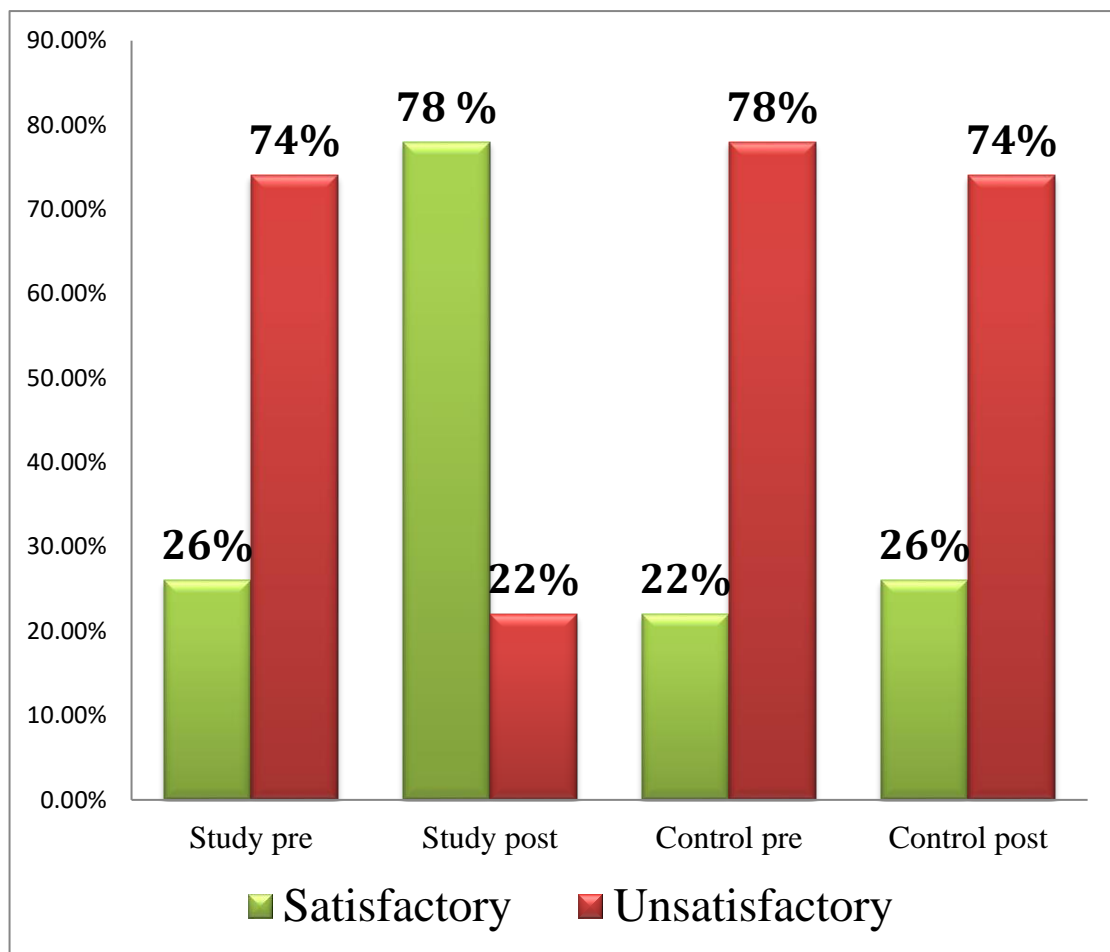Cancer Undergoing Chemotherapy: A Randomized Controlled Trial Study

Figure 2: Patients' self-management knowledge regarding chemotherapy and its management in the study and control groups throughout the study phases (n=100).

Table (3) Correlation between health literacy, self-management knowledge, and self-management behaviors post-intervention in the study group

Variables		Health Literacy	Self-management knowledge	Self-management behaviors
Health literacy				
Self-management knowledge				
	r.	0.612		
	p.	<0.01**		

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Self-management behaviors

	r.	0.499	0.267
	p.	<0.01**	<0.05*

r = Correlation coefficient. *Significant at $p < .05$. **Highly significant at $p < .01$.

Table (4): Best fitting multiple linear regression model for the self-management knowledge.

Items	Unstandardized Coefficients	standardized Coefficients	T test	P. value
	B	B		
Residence (Urban)	.185	.130	2.600	.039*
Educational level (High)	.293	.237	5.987	.006**

Model	R²	Df.	F	P. value
Regression	0.37	2	7.600	.007**

*Significant at p ‹0.05. **Highly significant at p ‹0.01. Not significant at p>0.05

Table (5): Best fitting multiple linear regression model for the total self-management behaviors.

Items	Unstandardized Coefficients	standardized Coefficients	T test	P. value
	B	B		
Age	-.201	.142	2.754	.038*
Marital status (Married)	.183	.117	2.902	.036*
Educational level (High)	.250	.203	4.721	.011*

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Living with whom (Alone)	-.227	.181	3.661	.020*

Model	R²	Df.	F	P. value
Regression	**0.40**	3	8.290	.003**

*Significant at p ‹0.05. **Highly significant at p ‹0.01. Not significant at p>0.05

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