Original Article

The Effect of Health Literacy Counselling on Self-Care in Women after Mastectomy: a Randomized Clinical Trial

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ABSTRACT

Introduction: Breast cancer has a high prevalence, constituting a major cause of mortality in women around the world. Health literacy has a vital role in the self-care of chronic diseases such as cancer and is an essential element in the ability of each person to engage with health promotion. The aim of this study was to determine effect of health literacy counselling on self-care in women after mastectomy.

Methods: This study is a randomized, controlled, clinical trial carried out on 72 women with breast cancer after mastectomy in Fars province. The eligible women entered the study using convenience sampling and were then divided into an intervention and a control group through randomized blocks of four. Health literacy questionnaire and self-care questionnaire were distributed among the participants before, immediately after and three weeks following the intervention. Data analysis was performed in SPSS ver.13.

Results: The results showed no significant differences between the two groups in terms of their health literacy and self-care scores before the intervention (P=0.299 and 0.059). A comparison of the mean values showed a greater increase in the mean score of health literacy and score of self-care immediately and three weeks after the intervention in the intervention group compared to the control group. Also, the mean score of the dimensions of self-care in chemotherapy increased over time in the intervention group.

Conclusion: The findings of this study confirm the higher effectiveness of counseling with a health literacy approach on overall self-care in chemotherapy and all its dimensions.

Introduction

Malignancies are the most important health problem in the world. Breast cancer is a highly common malignancy in women, affecting one out of every eight women, which might lead to mortality.[1] This cancer is almost specific to women, and more than 99% of those affected are female; however, men are not exempted, and 1% of all breast cancer diagnoses and less than 0.01% of breast cancer-related deaths occur in men.[2] Although breast cancer has the lowest incidence rate in Iran compared to other Asian countries, the rise in its prevalence over the last four decades has made the disease a very frequent malignancy in women in Iran.[3]

Breast cancer treatment varies, depending on its severity. The main treatment involves breast surgery in the form of lumpectomy or mastectomy followed by chemotherapy.[4] Chemotherapy is an important systemic therapy with an increasing use in the treatment of cancer. This technique is the first choice for controlling and preventing the progress of cancer, but has severe side-effects that occur due to physiological changes in the body organs and systems.[5] The complications of chemotherapy include nausea and vomiting, fatigue, hanges in palate, alopecia, sexual dysfunction, memory loss, attention problems and inability to adhere to chemotherapy.[6-8] Chemotherapy may thus have the greatest effect on patients' quality of life and disrupt their physical, psychological, social and spiritual well-being.[9] Finding a way to reduce the severity of these complications is very important. Self-care is one of the key ways for reducing these problems.[10]

Self-care includes regular training and supportive interventions that the health care team offers to enhance the patients' adeptness and trust in managing their health problems and consists of constant monitoring of the existing problems, tracking their progress, goal-setting and providing support for solving the problems.[11]

Greater attention is paid to the concept of self-care in the modern world due to humans' need for maintaining and promoting their health, recovery, lack of health care facilities and hygiene, lack of adequate and equal access to facilities in all parts of the society and the substantial costs of health care services.[12]

Health literacy has a vital role in the self-care of chronic diseases such as cancer. For the daily management of a chronic or even a long-term disease, people must first have an understanding of their own health information.[13] Yet, 25% of patients cannot properly obtain and process essential information about their own

health verbally and in writing to make appropriate decisions, and this deficiency has made health literacy a major concern with regard to cancer.[14] Health literacy should not only be considered a personal attribute, but also a key health determinant across the community.

Health literacy plays a vital role in the self-care of chronic diseases, including cancer, and is an essential element in the ability of each person to engage with health promotion and prevention activities. Therefore, considering the high rate of breast cancer in Iran, on the one hand, and the direct impact of this disease on the health of the family and society, on the other, research on health literacy and self-care can lead to the discovery and identification of pathways which can improve the well-being of patients. Considering the importance of attention to the impact of health literacy for promoting health behaviors and the need to pay attention to the care methods used for women with breast cancer, and also the role of obstetricians as the main health care providers in women. The aim of this study was to investigate the effect of health literacy counselling on self-care in women after mastectomy.

Materials and methods

The ethics committee of Alborz University of Medical Sciences approved this research in a meeting held on March 4, 2017 (abzums.rec.1395.144), and the project was then registered at the Iranian Registry of Clinical Trials (IRCT2017022327728N5). Written informed consent was obtained from all the subjects.

The current randomized clinical trial was conducted in parallel on 72 eligible women presenting to select health centers of Fars Province in 2017.

Based on the difference between two means equation and similar studies, and taking into account a standard deviation of 10 for self-care, a difference of 7 points and a potential sample loss of 10%, the sample size was set as 32 per group. The participants were selected from among women with breast cancer undergoing mastectomy in select health centers of Fars Province.

The study inclusion criteria consisted of: being of Iranian nationality; being a woman with breast cancer who has undergone mastectomy; having received one session of chemotherapy; having no other underlying diseases; and being willing to participate in the study.

The study exclusion criteria consisted of not attending at least two sessions of the counselling provided; and not having filled out the questionnaires or having returned incomplete ones.

The data were collected, using the Iranian Health Literacy Questionnaire (IHLQ),[15] a researcher-made self-care in chemotherapy questionnaire, and a self-reporting checklist of personal-demographic details. The IHLQ contains 66 items with nine subsets, including: 1) access to health information sources; 2) application of sources; 3) reading literacy; 4) comprehension; 5) the ability to evaluate the content of health resources; 6) decision-making and communication skills; 7) health knowledge;

8) personal empowerment; and 9) social empowerment. In 2014, Haghdoost et al., confirmed the validity and reliability of this tool.[15]

Given the lack of a questionnaire for self-care in chemotherapy in Iran, the researchers designed a questionnaire using the available relevant questionnaires,[16,17] self-care book for chemotherapy of National Cancer Institute,[18] the existing self-care instructions for chemotherapy (Motahari Chemotherapy Clinic in Shiraz) and expert opinions. The developed questionnaire contained five dimensions, including: 1)digestive health; 2) physical, psychological and mental health; 3) skin health; 4) self-care knowledge; and[5] sexual health. Validity of the designed instruments was determined using face validity, content validity. Validity has both qualitative and quantitative aspects. The qualitative aspects are conceptual. The quantitative aspects are numerical for face validity, ten patients filled out the form, and for assessing the content validity, 10 faculty members in reproductive health, obstetrics/gynecology and oncology were asked to comment on the items. The reliability of the tool was assessed, using the Cronbach's alpha test. On 50 women who present in center for getting service

For sampling, the researcher visited Motahari Chemotherapy Clinic in Fars Province, and selected eligible patients through convenience sampling and briefed them on the research aims and got their written consents then if they satisfied, using permuted block randomization to randomly allocate a participant to a control group(routine counseling on mastectomy and chemotherapy based on the center's guidelines and the same educational self-care package given to the intervention group), while maintaining a balance across intervention groups(routine counseling on mastectomy and chemotherapy based on the center's guidelines plus counseling for health literacy on self-care). Each "block" has a specified number of randomly ordered treatment assignments.

Six 1.30-hour sessions were held for both the intervention and control groups. To avoid the two groups' coming into contact with each other, the counseling sessions were held on different days in groups of three to five. The subjects discussed in the intervention group included: session 1) group members and the leader getting to know one another, creating a positive rapport, announcing the group rules and motivating the members to actively participate in the sessions and be on time, giving further details on the disease, learning of the individual's feelings about the disease, and their understanding of the effect of the disease on their body. Session 2) providing counseling on health-related concepts, conveying basic information and getting to know the individual's thoughts about personal health and self-care, learning of their self-care problems and teaching ways to deal with them. Session 3) conveying basic information and getting to know the individual's thoughts about sexual health, hearing of

their sexual problems and emphasizing the need to identify, prevent and deal with these problems. Session 4) conveying basic information and getting to know the individual's thoughts about mental health (stress and depression), its symptoms and consequences, and emphasizing the need to identify, prevent and deal with them, understanding concepts related to communication skills, and understanding the effect of family and social support. Session 5) conveying basic information and getting to know the individual's thoughts about the complications of the treatments provided, emphasizing the need to identify, prevent and deal with them, and teaching them about the breast cancer care services available to them. Session 6) going over the subjects discussed, practicing the skills taught, answering questions, and getting feedback about the content of the sessions held. At the beginning of the sessions, right after the end of the sessions, and three weeks later, both groups filled out the IHLQ and the self-care in chemotherapy questionnaire. The researcher followed up the participants on the phone during the process. A total of 72 women entered the study, but eight were excluded in the process, including three participants from the intervention group for not completing the counseling sessions and one for not presenting to the center at the agreed-upon time, and four were excluded from the control group as well, because they did not wish to attend the sessions. The study was completed with 64 participants. Figure 1 shows the Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the study participants.
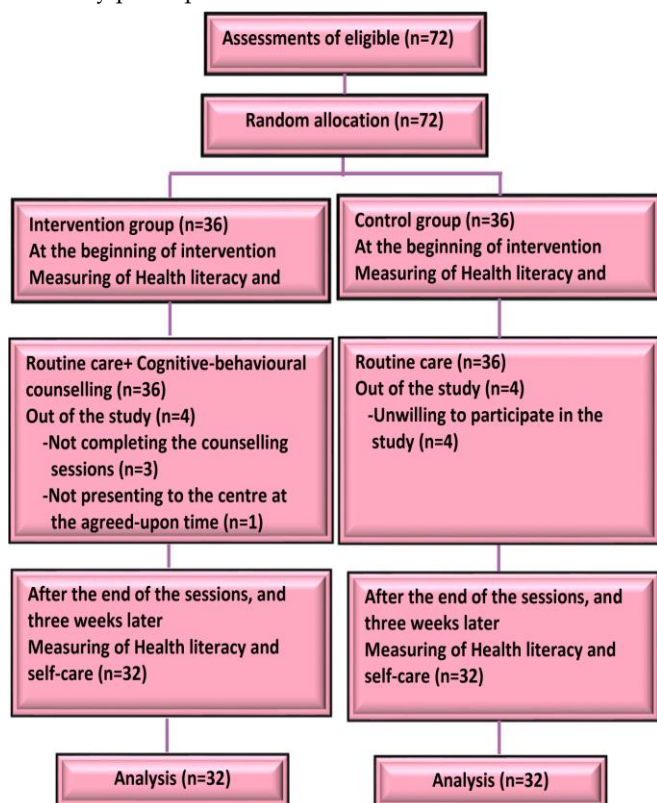

Figure 1. Flow chart of the study

SPSS Ver. 13 (version 13.0, Chicago, IL, USA) and Mann-Whitney's test, the Chi-square test and Repeated Measurement ANOVA were used for data analysis.

Results

This study was completed with participation of 64 women with breast cancer after mastectomy who had been to the first session of their chemotherapy. Mean age and standard deviation of sample was 41.47(8.72). After using Man-Whitney's test to ensure the normality of the assessed variables, and the Chi-square test were carried out and did not show a significant difference between the two groups with regard to mean age, education, occupation and income; in other words, the two groups matched in terms of these variables (Table 1).

Table 1. Issue distribution of women's demographic characteristics of breast cancer

Variable	Group		P-value
	Control N (%)	Intervention N (%)	
Patient's age			0.90
<30	3(8.33)	7(19.44)	
30-40	11(30.55)	8(22.22)	
>40	22(61.12)	21(58.34)	
Patient education			0.59
Illiterate	4(11.11)	4(11.17)	
Less than a diploma	20(55.56)	18(50)	
Diploma	10(27.77)	9(25)	
Bachelor	2(5.56)	5(13.8)	
Job status			0.16
Housekeeper	17(47.22)	19(52.8)	
Retired	7(19.44)	4(11.11)	
Unemployed	3(8.33)	3(8.33)	
Employed	3(8.33)	5(13.88)	
Temporary employed	6(16.68)	5(13.88)	
Income			0.21
Weak	25(69.40)	21(58.33)	
Average	9(25)	10(27.77)	
Good	2(5.6)	5(13.9)	
Nationality			0.99
Fars	27(75)	26(72.17)	
Turkish	2(5.50)	3(8.33)	
Lor	7(19.5)	7(19.5)	

Chi-square test, was used for data analysis

In the quantitative face validity assessment, the impact score was calculated as 2.2 to 5 for all the items, and since these values were greater than 1.5, all the items were kept. In the content validity assessment, the items' CVR, ranging from 0.8 to 1, was greater than 0.62 and their CVI which ranged from 0.76 to 1 was greater than 0.7, leading to no items being eliminated, as a result. The Cronbach's alpha internal consistency of the researcher-made questionnaire was calculated as 0.83, and the tool was thus approved for use in extensive research.

The results showed no significant differences between the two groups in terms of their health literacy and self-care scores before the intervention (P=0.299 and 0.059). In other words, at baseline, the two groups had similar health literacy and self-care knowledge. In the intervention group, the mean score of the dimensions of health literacy increased immediately and three weeks after the intervention. The two groups differed significantly in terms of the overall mean scores of health literacy over time (P<0.001). A comparison of the mean

values showed a greater increase in the mean score of health literacy immediately and three weeks after the intervention in the intervention group compared to the control group, which is indicative of the effectiveness of counseling in the intervention group (Table 2).

Table 2. Comparison of mean score of general dimensions of health literacy in two groups before, immediately and three weeks after intervention in women with breast cancer

Health literacy dimensions	Before intervention Mean(SD)	After intervention Mean(SD)	3 Weeks after intervention Mean(SD)	Statistical indicators*
Access to information resources				P<0.001,F=46.55
Control group	1.87(0.16)	2.06(0.18)	2.03(0.18)	
Intervention group	1.94(0.14)	3.129(0.12)	2.37(0.18)	
Information acquisition				P<0.001,F=26.03
Control group	2.03(0.12)	2.34(0.17)	2.15(0.12)	
Intervention group	2.37(0.17)	3.31(0.2)	3.06(0.19)	
Ability to read				P<0.001,F=114.69
Control group	2.91(0.32)	3.87(0.35)	3.56(0.33)	
Intervention group	4.47(0.63)	9.56(0.47)	9.12(0.44)	
Ability to understand				P<0.001,F=107.86
Control group	8.69(0.29)	9.28(0.27)	8.69(0.28)	
Intervention group	9.37(0.8)	14.47(0.67)	13.31(0.64)	
Judgment and evaluation				P<0.001,F=81.20
Control group	4.56(0.23)	5.03(0.21)	4.75(0.2)	
Intervention group	5.62(0.60)	9.12(0.41)	8.72(0.37)	
Ability to make decisions				P<0.001,F=34.88
Control group	3.34(0.17)	3.69(0.18)	3.12(0.2)	
Intervention group	4.12(0.32)	11.75(0.27)	10.81(0.27)	
Individual empowerment				P<0.001,F=12.65
Control group	3.82(0.49)	4.12(0.18)	3.99(0.61)	
Intervention group	2.12.(0.45)	9.65(0.38)	9.11(0.55)	
Knowledge				P<0.001,F=92.41
Control group	4.25(0.28)	4.80(0.81)	4.4(0.2)	
Intervention group	3.71(0.18)	8.52(0.43)	7.54(0.35)	
Social empowerment				P<0.001,F=57.17
Control group	1.25(0.17)	1.43(0.18)	1.16(0.15)	
Intervention group	2.19(0.32)	4.78(0.27)	4.5(0.25)	
Total health literacy				P<0.001,F=25.42
Control group	1.25(0.17)	1.43(0.18)	1.16(0.15)	
Intervention group	2.19(0.32)	4.78(0.27)	4.5(0.25)	

Repeated Measurement was used for data analysis, *All dimensions were statistically significant

In the current study, the intervention and control groups showed significant differences in terms of the mean overall score of self-care over time (P<0.001). A comparison of the mean values showed a greater increase in the mean score of self-care immediately and three weeks after the intervention in the intervention group compared to the control group. Also, the mean score of the dimensions of self-care in chemotherapy increased over time in the intervention group (P<0.001), which indicates the effectiveness of counseling in the intervention group (Table 3).

Table 3. Comparison of mean scores of self-care dimensions in two groups before, immediately and three weeks after intervention in women with breast cancer

Self-care dimensions	Before intervention Mean(SD)	After intervention Mean(SD)	3 Weeks after intervention Mean(SD)	Statistical indicators*
Digestive health				P<0.001,F=118.97
Control group	10.62(0.41)	10.81(0.37)	10.03(0.34)	
Intervention group	9.72(0.76)	17.82(0.49)	16.62(0.43)	
Physical-mental-psychological health				P<0.001,F=129.21
Control group	9.69(0.49)	10.21(0.48)	9.81(0.47)	
Intervention group	9.78(0.70)	17.87(0.47)	16.93(0.43)	
Skin health				P<0.001,F=41.95
Control group	0.84(0.15)	1.03(0.14)	0.9(0.47)	
Intervention group	1.44(0.17)	2.56(0.14)	2.5(0.13)	
Self-care knowledge				P<0.001,F=214.15
Control group	20.56(0.55)	21.69(0.56)	20.9(0.52)	
Intervention group	19.28(0.99)	32.81(0.57)	31.41(0.51)	
Sexual health				P<0.001,F=509.52
Control group	2.47(0.27)	2.93(0.23)	2.69(0.22)	
Intervention group	1.37(0.27)	9.75(0.27)	9.34(0.27)	
Total self-care				P<0.001, F=405.23
Control group	44.19(0.94)	46.69(0.93)	44.34(0.84)	
Intervention group	41.59(2.16)	80.81(1.16)	76.81(1.08)	

Repeated measurement was used for data analysis, *All dimensions were statistically significant

Discussion

Breast cancer is a remarkable exception that shows the positive slope of health education.[19] Following their diagnosis, breast cancer patients have a number of important treatment decisions to make. Accurate, reliable and comprehensible information is vital to these patients.[20] Access to health information, treatment literacy and the ability to understand this information are vital to the individual's health management.[21] Addressing these information needs helps cancer patients gain control of their condition and enhances their participation and self-care.[22]

According to the results obtained, the two groups had no significant differences before counseling in terms of their self-care score; in other words, the two groups were matching in terms of their self-care knowledge at baseline, but after the intervention, the scores obtained in the digestive health, physical, psychological and mental health, skin health, self-care knowledge, sexual health and general self-care dimensions showed a greater increase in the intervention group compared to the controls immediately and three weeks after counselling.

Since the two groups had been matched in this regard before the intervention, the result is indicative of the role and effectiveness of counseling and the presence of a counselor in promoting self-care compared to when only an educational package is offered. In line with the present findings, many studies have pointed to the positive effects of self-care interventions on the management of symptoms in patients with cancer.[23-25] In a study entitled "The effectiveness of a self-care intervention to improve cancer pain management", Miaskofski et al., found that the pain intensity score reduced significantly in the intervention group compared to the controls against the baseline score, and concluded that using a psychological intervention within a self-care framework can improve the management of cancer pain.[26] Also, in a randomized trial entitled "Evidence suggests that a self-management program can reduce hospital stay and improve health in patients with chronic diseases", Lorig et al., found an improvement in health behaviors and the health status of patients receiving treatment compared to the controls, and a reduction was observed in the frequency of admission and the number of hospitalization days.[27]

The findings of this latter study agree with the results obtained in the study by Haghighi et al., on the effect of group counseling on depression in patients with breast cancer. They found a significant reduction in the depression score in the intervention group following therapy, but the level of depression showed no changes in the control group.[28]

In the current study, the two groups did not have significantly different health literacy scores before the intervention; that is, the two groups were matching in terms of their health literacy. After the intervention, however, a greater increase was observed in the mean health literacy score of the intervention group compared to the controls immediately and three weeks after the intervention. Since the groups were matched for demographic characteristics and health literacy, these results indicate the role and effectiveness of counseling in the presence of a midwife counselor on health literacy in patients after mastectomy. Many studies have addressed the effect of health literacy on diseases; for example, in their study entitled "Health literacy and cancer communication", Davis et al., argued that interventions addressing the subject of health literacy offer a great opportunity for achieving the goal of controlling cancer.[29]

A multivariate analysis conducted by Gazmararian et al., entitled "Health literacy and knowledge of chronic disease" showed that health literacy has an independent relationship with knowledge of diseases. They found massive opportunities for improving the patients' knowledge about their chronic diseases and concluded that attempts should be made to increase the patients' health literacy skills.[30]

The strengths of this research are that the two groups were similar with respect to confounding personal-demographic variables, including age, education, occupation and income and the main variables health literacy and self-care, which could have otherwise affected the results. The results obtained are thus assumed to be independent of the effect of these variables. Attempts were made in this study to match the participants, but the various educational media existing today and their potential effects may constitute a limitation of this research.

Conclusion

The findings of this study confirm the higher effectiveness of counseling with a health literacy approach in the presence of a midwife counselor compared to educational packages offered with routine counseling on overall self-care in breast cancer related chemotherapy and all of its dimensions. Providing counseling with the help of experts such as obstetricians as the main health care providers in women can substantially help increase health literacy and subsequently improve self-care in chemotherapy. It is suggested that self-care education be provided to patients' family during this period, which will further support patients.

Acknowledgments

Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

Research Highlights

What is the current knowledge?

Breast cancer is a highly common malignancy in women, affecting one out of every eight women, which might lead to mortality.

What is new here?

Counseling with a health literacy approach has effectiveness on overall self-care in chemotherapy and all its dimension.

Author's contributions

All the authors contributed to the conception and design of the study. ZM and MR wrote the first draft of the paper. NSh and SE revised the manuscript. KK and ZM have analyzed the research data. All authors read and approved the final manuscript.

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