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Forming a Stress Management and Health Promotion Program for Women Undergoing Chemotherapy for Breast Cancer: A Pilot Randomized Controlled Trial

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Abstract

Objective. To assess the effects of an 8-week stress management and health promotion program on women undergoing breast cancer chemotherapy treatment. *Patients and methods*. A total of 61 patients were recruited in 2 cancer centers and were randomly assigned to the intervention program (n = 30) or control group (n = 31). The intervention program consisted of different stress management techniques, which were combined with instructions for lifestyle modification. Assessments were carried out through questionnaires and measurement of body mass index (BMI) at baseline and at the end of the 8-week program. *Results.* In all, 25 participants completed the intervention program, whereas 28 participants completed the observational control program. The intervention program resulted in a small effect size on internal dimension of Health Locus of Control (HLC) and a medium effect size on stress, depression, anxiety, night sleep duration, and chance dimension of HLC. A strong effect size was recorded for BMI and sleep onset latency. Self-rated health, spiritual well-being, and powerful others dimension of HLC were not significantly affected. Additionally, some of the participants reported a reduction in the side effects caused by chemotherapy. *Conclusions.* The intervention resulted in several benefits for the general health status of patients. Therefore, it should be considered as feasible and potentially beneficial for women undergoing breast cancer chemotherapy. However, it is necessary for this intervention to be tested through a randomized controlled trial in a larger sample of patients before adopting this program in standard cancer care.

Keywords

stress, health promotion, breast cancer, chemotherapy, BMI, sleep, health locus of control

Introduction

Female breast cancer constitutes a major threat to public health in many developed countries. In Europe, it has been registered as the most prevalent type of cancer regardless of sex,[1] whereas in the United States, 232 670 new cases were expected for 2014, accounting for 29% of cancer incidence in women within this year.[2]

Intense stress has a damaging effect on the human body and is considered as a causative factor for many disorders,[3] and with regard to breast cancer, it is strongly associated with the occurrence of the disease.[4] In addition, it has been held responsible for increased possibility of disease relapse.[5,6] Thus, stress management after the onset of breast cancer should be considered of high importance because it may have an indirect impact on the patient's disease status and survival.

With regard to stress during treatment, chemotherapy has been reported as a period where most women, even at disease stage I and II, experience distress at some point.[7] A study that compared breast cancer patients receiving chemotherapy with others who were not found that stress levels

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were significantly higher for the first group.[8] During that period, stress management is extremely necessary because increased stress has been related to decreased efficiency of chemotherapy.[9] Moreover, one study showed that patients with breast cancer and patients receiving chemotherapy had increased levels of anxiety and depression compared with those with cancer at other sites and other treatment regimens.[10] Barring mental health issues, weight gain[11] and sleep disruption[12] occur very often during chemotherapy, threatening the general health status of patients.

Apart from the above-mentioned common parameters of the research, several studies have focused on beliefs and attitudes that help patients with breast cancer to fight back. Spiritual aspects contribute to improved mental health outcomes,[13] whereas self-rated health (SRH) should not be ignored because of its correlation to exercise levels and hot flashes.[14] Furthermore, a comparison of breast cancer patients with healthy controls showed that the former had lower scores on internal dimensions and higher scores on external dimensions of Health Locus of Control (HLC), a finding that may be associated with poor emotional adjustment to the disease.[15] Thus, even though no cause-effect relationships have been established for the above variables, maintaining a good physical and psychological status after the onset of breast cancer should be considered as having complex and multifactorial causes.

To date, a variety of techniques have been tested to counter the threats and improve the health condition of patients during breast cancer chemotherapy. There are short time-saving interventions, such as expressive writing,[16] whereas psychoeducational[17] and physical activity programs[18] might take longer. There is also a diversity in how these techniques operate because some of them, for example, cognitive behavioral therapy (CBT),[19] mainly focus on the patient's thoughts and cognitive distortions, whereas others, such as progressive muscle relaxation (PMR),[20] primarily affect the patient's physiology. Studies to determine effectiveness of these interventions implement each one exclusively. Research has not examined whether use of a variety of these interventions simultaneously offers patients additional benefits.

Based on the aforementioned needs, we have formulated an 8-week stress management and health promotion program for breast cancer patients undergoing chemotherapy, using both conventional and nonconventional medical techniques, and we tested it in a pilot randomized controlled trial.

Methods

Participants

Female breast cancer patients were recruited from Attikon University Hospital and Sotiria General Hospital in Greece. In total, 61 participants entered the study and were randomly assigned to the intervention (n = 30) or control group (n = 31).

The inclusion criteria were as follows:

1. Histological diagnosis of breast cancer
2. Undergoing chemotherapy for at least 8 weeks after entering the study
3. Age between 18 and 75 years
4. Resident of Attica

The exclusion criteria were as follows:

1. Diagnosis of mental disorder (eg, posttraumatic stress disorder)
2. Use of antipsychotics, anxiolytics, or antidepressants
3. Systematic use of a stress management technique during the previous 6 months (eg, expressive writing, meditation, PMR)

Procedures

The study was carried out by a multidisciplinary team, which included a psychologist (PP) and a health visitor (GZ) qualified in stress management and health promotion, as part of their thesis in the Postgraduate Course "Science of Stress and Health Promotion," School of Medicine, University of Athens. Both of them received the same training on how to perform the program from their professors (GC and CD). Each participant received the intervention from the psychologist and the health visitor at the same time. Both were external researchers. The study complied fully with the Declaration of Helsinki,[21] and approval was obtained from School of Medicine, University of Athens, and the scientific and bioethical committees of both hospitals. The intervention visits and assessments were conducted in Greek. All recruited patients were fully informed about the study and gave their written informed consent. Patients were not funded for participating in the study. Various expenses arising from their involvement in the study (mainly transportation expenses) were not covered. All patients were provided with written questionnaires, which they were requested to fill in and return at the next meeting with the researchers. Before the beginning of the study, the 2 primary researchers (PP and GZ), under the guidance of their professor (CD), proceeded with randomization using an online random generator found on the Internet (www.random.org). Through this process, all patients were randomized to either an 8-week stress management and health promotion program or a control group. In the latter group, an approximately 15-minute placebo-effect meeting was carried out with the primary researchers (PP and GZ) every time patients visited the oncology unit for chemotherapy. These ranged from 3 to 6 for each person, depending on their chemotherapy sessions. These meetings had a

Table 1. Intervention Schedule Overview.

Week	Technique or Modification	Details	Length of Practicing
First week	Physical activity	Walking at least 8300 to 10000 steps per day measured by a step pedometer provided	Until the end of the study
Second week	Diaphragmatic breathing	Practicing twice a day	Until the following week
Third week	Progressive muscle relaxation	Practicing twice a day	Until at least week 6
Fourth week	CBT	Reconstruction of distortions during the appointment	
Fifth week	Dietary consulting	Adoption of changes in everyday eating habits	Until the end of the study
Sixth week	Guided imagery	Practicing twice a day instead of PMR or continuing practicing PMR if preferred	Until the end of the study
Seventh week	No intervention	Telephone contact	
Eighth week	No intervention		

Abbreviations: CBT, cognitive behavioral therapy; PMR, progressive muscle relaxation.

general educational content on cancer-specific topics. All patients from both groups entered the study at the same time. By the end of the 8-week period, they were given questionnaires, which were to be returned at the next appointment.

Intervention Group

The intervention group received an 8-week stress management and health promotion program. This consisted of 6 weekly, 30-minute sessions, starting at the first and ending at the sixth week, carried out in the oncology unit. These sessions were not received on the same day as their standard chemotherapy treatment. Each session had a stress management technique or instructions about a lifestyle modification, which was to be incorporated in the everyday schedule of the participant. If patients missed an appointment they were immediately contacted by phone, and the appointment was rearranged within the following 2 working days. An overview of the intervention schedule can be found in Table 1.

During the first session, the participants received some written material containing information about the 8-week program they had to follow. To increase the participants' awareness and motivation, they were also informed verbally and in writing about stress and its relation to the onset and relapse of breast cancer. Additionally, they were given information verbally and in writing about physical activity benefits and a step pedometer to control their physical activity more efficiently. Based on a recent trial, which portrayed major benefits in chemotherapy side effects, mobility, pain, and weight control,[22] they were encouraged to walk at least 8300 to 10 000 steps daily for the next 8 weeks. For patients with kinetic limitations or advanced stage of disease, the goals were accordingly adjusted. A gradual increase in physical activity was suggested for those who were completely physically inactive.

Subsequently, participants were informed verbally and in writing about diaphragmatic breathing (DB), its difference to thoracic breathing, and its benefits for modulating the autonomic nervous system.[23] Moreover, they were informed about the associated beneficial findings, including improvement in tension-anxiety and fatigue in women undergoing chemotherapy for various types of cancer.[24] Because of the above, they were motivated to practice DB twice a day (morning and evening) till the following week.

In the next session, participants were taught PMR and given an audio CD with instructions on how to practice the technique. The CD contained 10 minutes of DB practice and 15 minutes of PMR. Given the impressive benefits, as reported in studies, for women undergoing breast cancer chemotherapy who practice the technique (eg, reduction in side effects), participants were encouraged to practice PMR twice a day (morning and evening).[20,25]

The next step included a CBT session where common cognitive distortions, which mainly concerned temporary hair loss, perceived acceptance from others because of body image changes, and the 5-year survival rate, were identified. The reconstruction of these distortions was based on CBT techniques.

In the following session, participants were provided with verbal and written guidelines about healthy diet modifications (eg, increasing the intake and variety of fruits and vegetables). These modifications were based on a recent nutrition counseling study in breast cancer patients, which resulted in an increased intake of fruits and vegetables and an allegedly healthier diet.[26]

Next, based on the findings of 2 previous randomized controlled trials demonstrating a beneficial effect on nausea, vomiting, and quality of life,[27,28] guided imagery (GI) was used through an audio CD combining relaxation training with the visualization of pleasurable scenes (eg, a sunny beach). Participants were encouraged to practice this technique twice a day (morning and evening) instead of PMR.

Subsequently, a spare week was left where no technique or modification was introduced. The participants were reminded by phone of the need to comply with the program until its end. In the eighth week, participants completed the

final assessment questionnaires. All of them kept the written material, both CDs and step pedometers, after the completion of the program.

Study Measurements

Assessment of Sociodemographic, anthropometric, and medical variables was performed at baseline. All other variables, including body mass index (BMI), were assessed both before and after the intervention. At the second assessment, the intervention group was also given questions about the participants' opinion on the program, whereas all other questions were given to both groups.

Sociodemographic, Anthropometric, and Medical Variables. These variables included age, marital status, cohabitation status, level of education, smoking status, BMI, chemotherapy regimen, cancer stage, and whether the patient had undergone surgery, hormone therapy, and radiotherapy. Scale and height chart measure was used by a specialized nurse to assess BMI. The women's medical records (eg, chemotherapy regimen) as well as their self-reports were used, when necessary (eg, cohabitation status).

Self-rated Health. The participants graded their SRH for the past year using a Likert scale, with 1 denoting *extremely poor* to 10 denoting *excellent*.

Night Sleep Duration. The recording of night sleep duration was undertaken by using the following question: "During the last 7 days, how many hours did you usually sleep every night?". It was also mentioned that the specific question referred to the actual sleeping hours and not to the hours lying in bed.

Sleep Onset Latency. Sleep onset latency was assessed using the following question: "During the last seven days how many minutes were needed on average in order to fall asleep at night?"

Depression, Anxiety, and Stress Scale 21. The Depression, Anxiety, and Stress Scale 21 (DASS-21) is the brief version of DASS-42. It is a self-reported 21-item measure, which has been designed to assess the negative emotion state of Depression, Anxiety, and Stress and has been translated and validated into the Greek language.[29] Each of the 3 aforementioned subscales consists of 7 statements that contain context and possible answers ranging from 0 (*did not apply to me at all*) to 3 (*applied to me very much or most of the time*). The depression subscale assesses dysphoric mood, hopelessness, lack of interest, anhedonia, devaluation of life and self, and inertia. The anxiety subscale measures autonomous arousal, skeletal muscle effects, situational anxiety, and subjective experience of anxiety. The stress subscale assesses difficulty in relaxing, irritability/overreaction, easy agitation, nervous arousal, and impatience. For depression, Cronbach's α coefficients were 0.72 (initial) and 0.73 (final); for anxiety, 0.71 (initial) and 0.73 (final); and for stress, 0.71 (initial) and 0.72 (final).

Health Locus of Control. A Greek translation and validation of multidimensional HLC was used to assess participants' self-reported HLC.[30,31] It included 18 questions, with possible answers ranging from 1 ("disagree very much") to 6 ("agree very much"). HLC consisted of 3 dimensions (internal, chance, and powerful others). The score of these dimensions was calculated separately for each one. For internal HLC, Cronbach's α coefficients were 0.77 (initial and final); for chance, 0.73 (initial) and 0.76 (final); and for powerful others, 0.72 (initial) and 0.73 (final).

Spiritual Well-being Scale. A Greek translation and validation of the Spiritual Well-being Scale (SWBS) was used.[32] This scale included 20 questions, with possible answers ranging from 1 (*disagree very much*) to 6 (*agree very much*). The subscales, which included 10 questions each, measured religious well-being and existential well-being. The total score of the questionnaire, which was calculated by the total sum of all questions, represents the spiritual well-being. For the religious well-being subscale, Cronbach's α coefficients were 0.73 (initial) and 0.74 (final), and for the existential well-being subscale, they were 0.81 (initial) and 0.83 (final). For SWBS, the total Cronbach's α coefficient was 0.84 (initial and final).

Questions Concerning Participants' Opinion About the Program. To collect data on participants' opinion about the program, 3 questions were posed: (*a*) Would you practice the same program a second time? (*b*) Would you suggest this program to a friend of yours if she had the same disease? and (*c*) In which way do you believe you benefitted from the program? The first 2 questions had a "yes" or "no" answer, whereas question (*c*) had an empty space for the participant to fill in.

Statistics

All statistical calculations were performed using the SPSS for Windows (version 21) statistical software (SPSS Inc, Chicago, IL). Sociodemographic, anthropometric, and medical variables and baseline group characteristics are presented as mean, range, absolute values and proportions. Pearson's χ^2 test and nonparametric Mann-Whitney U tests were used for baseline comparisons between the 2 groups. The changes (after 8 weeks minus baseline) in BMI, SRH, night sleep duration, sleep onset latency, DASS-21, HLC subcategories, and SWBS were used as outcomes. Nonparametric Mann-Whitney *U* tests were used for comparisons between the outcomes of the 2 groups. Effect sizes were calculated according to the formula $r = Z/n^{0.5}$ (0.1, 0.3, and 0.5 denoted

small, medium, and large effect sizes, respectively). The *P* value of significance was set at .05 for all analyses.

With regard to the choice of statistical calculations, having considered that this research did not focus on objective evaluated outcomes (eg, death, disease recurrence), a withdrawal from any of the groups led to withdrawal from the study because after having quit, patients were unwilling to arrange an appointment for the end-point assessments. In addition, there were no multiple measures allowing the use of last observation carried forward. For these reasons, statistical calculations were done with the above-described method because it was impossible to justify the use of intent-to-treat analysis.[33,34]

As regards the questions on participants' opinion in relation to the program, descriptive statistics were used to analyze them. For the last question, the development of encoding categories was used to analyze the data.[35] Three members of the research team met and had a discussion to convert the original data (the first 2 authors and the fourth author). The agreement between the researchers on delimiting units of analysis and coding them reached almost 95%. In the instance of a nonagreement on the encoding, the authors returned to the original data until an agreement could be reached.

Results

Participants' Characteristics

In all, 69 potential participants who met the inclusion criteria were approached; 8 of them were not included in the study. This was because 5 declined to participate, 1 was currently using psychotropic drugs (antidepressants), 1 had a currently diagnosed mental disorder (panic disorder), and 1 was systematically using another stress management technique (transcendental meditation). The final number of participants included in the study was 30 for the intervention and 31 for the control group (n = 61). They were randomly assigned to the 2 groups. A total of 25 participants in the intervention group completed the final assessments (drop-out rate 16.7%), whereas 28 participants in the control group completed the 8-week follow-up (drop-out rate 12.9%). All participants in the intervention group received the full intervention program. Of those who dropped out from that group, 3 of them reported inability to complete the program, 1 of them did not give further explanation, and 1 discontinued as a result of severe worsening of her medical condition. As for the control group, 1 said that she was too tired to complete the final questionnaires, 1 that she was bored, and 1 that she did not have time to do so.

Baseline Analyses

No significant differences between the 2 groups were found in baseline assessments of the participants. Taking into account sociodemographic, anthropometric, and medical characteristics, most women from both groups were approximately 55 years old and had a low educational level. The majority of the women were married, nonsmokers, in stage II and III and were receiving adjuvant chemotherapy, whereas some were receiving other lines of treatment from first to fourth. Most of them had not received hormone therapy or radiotherapy before their current treatment. Almost all had undergone breast surgery before their chemotherapy treatment. For the intervention group, the mean value of BMI indicated that they were, on average, close to overweight, whereas the control group was slightly overweight. More information about the preintervention scores and differences between the 2 groups can be found in Table 2.

End-point Analyses

The end-point analyses are presented in Table 3. As reported, the stress management and health promotion program had a small size effect on internal dimension of HLC (0.28) and a medium size effect on stress (0.43), depression (0.35), anxiety (0.39), night sleep duration (0.48), and chance dimension of HLC (0.49). A strong effect size was recorded for BMI (0.57) and sleep onset latency (0.50). SRH, SWBS, and powerful others dimension of HLC were not significantly affected.

Questions Relating to Participants' Opinion About the Program

A total of 22 out of 25 participants stated that they would participate in the program again (88%), whereas 21 would suggest it to a friend if she had the same disease (82%). Their opinions about the benefits they gained after the intervention are presented in Table 4.

Discussion

The present intervention and control condition study shows for the first time that the combination of conventional (CBT) and nonconventional (DB, PMR, and GI) stress management techniques together with lifestyle modifications (diet, physical activity) might have an impact on the general health status of patients. This combination of techniques and healthy lifestyle modifications could be considered by some patients to be more appealing than a simpler intervention (eg, GI alone). On the program evaluation questions, most participants stated that they would do it again and suggest it to a friend, indicating that they were satisfied with this intervention. It should also be noted that the present study had a very high participation rate for which no obvious explanation can be found.

Because of the heterogeneity of the intervention compared with other programs regarding its sample, duration of

Table 2. Baseline Assessments.

Measures	Intervention Group (n = 25)	Control group (n = 28)	*P* Value
Age, mean (range)	56.64 (40)	55.25 (34)	.363
Level of education			
Primary or secondary (%)	21 (84%)	25 (89.29%)	.404
Tertiary (%)	4 (16%)	2 (7.14%)	
Master's/PhD (%)	0	1 (3.57%)	
Family status			
Single (%)	1 (4%)	2 (7.14%)	.911
Married (%)	16 (64%)	18 (64.29%)	
Divorced (%)	4 (16%)	5 (17.86%)	
Widowed (%)	4 (16%)	3 (10.71%)	
Cohabitation status			
With someone else (%)	25 (100%)	25 (89.29%)	.238
Alone (%)	0	3 (10.71%)	
Chemotherapy regimen			
Adjuvant (%)	17 (68%)	21 (75.10%)	.13
First line (%)	5 (20%)	1 (3.57%)	
Second line (%)	2 (8%)	4 (14.28%)	
Third line (%)	1 (4%)	0	
Fourth line (%)	0	2 (7.14%)	
Cancer stage			
Stage I	1	0	.763
Stage II	13	14	
Stage III	10	11	
Stage IV	1	3	
Had undergone breast surgery			
No (%)	0 (0%)	3 (10.71%)	.238
Yes (%)	25 (100%)	25 (89.29%)	
Had received hormone therapy			
No (%)	18 (72%)	22 (78.57%)	.751
Yes (%)	7 (28%)	6 (21.43%)	
Had received radiotherapy			
No (%)	17 (68%)	22 (78.57%)	.534
Yes (%)	8 (32%)	6 (21.43%)	
Smoking status			
Never (%)	17 (68%)	19 (67.86%)	.58
In the past (%)	4 (16%)	7 (25.10%)	
Currently (%)	4 (16%)	2 (7.14%)	
BMI, mean (range)	24.76 (12.92)	25.78 (11.73)	.428
SRH, mean (range)	4.24 (8)	4.68 (9)	.262
Night sleep duration, mean (range)	5.99 (6)	6.25 (6)	.493
Sleep onset latency, mean (range)	30.28 (92)	27.96 (80)	.642
DASS 21 score, mean (range)	60.8 (58)	56.29 (68)	.532
Depression score, mean (range)	18.88 (22)	17.86 (32)	.451
Anxiety score, mean (range)	15.52 (28)	13.43 (24)	.436
Stress score, mean (range)	26.4 (26)	25 (28)	.629
HLC			
Internal, mean (range)	18.2 (12)	18.71 (16)	.623
Chance, mean (range)	23.04 (15)	22.29 (17)	.507
Powerful others, mean (range)	23.36 (11)	24.5 (19)	.361
SWBS, mean (range)	67.2 (43)	71.11 (50)	.682
Religious well-being, mean (range)	32.76 (25)	34.07 (27)	.573
Existential well-being, mean (range)	34.44 (28)	37.04 (24)	.068

Abbreviations: BMI, body mass index; DASS, Depression, Anxiety, and Stress Scale; SRH, self-rated health; HLC, Health Locus of Control; SWBS, Spiritual Well-being Scale.

Table 3. Outcomes of Analyses.

Measures	Intervention Group	Control Group	Significance Level	Size Effect, *r*
Δ Mean BMI (SD)	−0.21 (0.38)	0.11 (0.23)	0.000*	0.57
Δ Mean SRH (SD)	0.56 (1.61)	0.25 (1.55)	0.290	0.15
Δ Mean Night sleep duration (SD)	0.89 (0.89)	0.02 (0.68)	0.000*	0.48
Δ Mean Sleep onset latency (SD)	−12.12 (16.6)	2.35 (9.74)	0.000*	0.50
Δ Mean DASS-21 score (SD)	−12.16 (10.15)	1.93 (8.7)	0.000*	0.59
Δ Mean Depression score (SD)	−3.12 (6.66)	1.5 (4.83)	0.01*	0.35
Δ Mean Anxiety score (SD)	−2.96 (4.76)	1.35 (3.69)	0.005*	0.39
Δ Mean Stress score (SD)	−6.08 (7.73)	−0.92 (5.56)	0.002*	0.43
HLC				
Δ Mean Internal (SD)	2.48 (4.40)	−0.39 (4.00)	0.041*	0.28
Δ Mean Chance (SD)	−2.96 (5.23)	1.89 (3.22)	0.000*	0.49
Δ Mean Powerful others (SD)	−0.6 (3.51)	−0.5 (2.38)	0.971	0.05
Δ Mean SWBS (SD)	6.88 (14.8)	3.43 (6.67)	0.487	0.10
Δ Mean Religious well-being (SD)	4 (8.21)	2.1 (4.54)	0.803	0.03
Δ Mean Existential well-being (SD)	2.88 (8.08)	1.32 (3.93)	0.432	0.11

Abbreviations: BMI, body mass index; SD, standard deviation; DASS, Depression, Anxiety, and Stress Scale; SRH, self-rated health; HLC, Health Locus of Control; SWBS, Spiritual Well-being Scale.

Table 4. Self-reported Benefits.

Benefits	Frequency (%)
Improvement in sleep	9 (36%)
Improvement in psychological state	8 (32%)
Reduction in side effects	7 (28%)
Weight control	4 (16%)
No benefits	3 (12%)
Gained knowledge about health	3 (12%)
Boost to smoking cessation	2 (8%)
Improvement in work performance	1 (4%)
Improvement in interpersonal relationships	1 (4%)

follow-up, assessments, and techniques used, head-to-head contrasts should be avoided, allowing however, for a few comparisons. In our study, the strongest effect size was observed in BMI and sleep, which should not be considered as unique. Similar positive changes in sleep have been reported after several interventions in women undergoing breast cancer chemotherapy,[25,36,37] whereas weight control has also been successfully achieved in other randomized controlled trials.[38,39] Although the beneficial findings in these dimensions are similar to those from previous studies, their importance should not be overlooked, taking into account that there is strong evidence supporting the fact that being overweight and obese after a breast cancer diagnosis predicts cancer and noncancer mortality.[40] As for sleep, there is also evidence that insufficient sleep might be associated with increased breast cancer mortality.[41] However, it remains unclear if the changes mentioned can be sustained, leading to a protective effect and healthier outcomes. In addition, although this reported weight change is statistically significant, it is doubtful whether such a small change in BMI could be protective against mortality hazards.

Depression, anxiety, and stress, as the main counterparts of the mental state, were found to be reduced in the intervention group. Another study with a similar design, using CBT together with relaxation training, reported a reduction in stress and anxiety scores of breast cancer patients.[42] As regards depression, a study exploring its prevalence during breast cancer chemotherapy found that 37.5% of women suffered from clinically significant depression requiring drug therapies.[43] Navari et al[44] found a significant improvement in depressive symptoms of breast cancer patients after the use of fluoxetine. As shown by the study results, this pilot randomized controlled trial also reduced depression. Nevertheless, apart from helping in depression coping, this 8-week stress management and health promotion program improved other important parameters as well.

In this context, there was an increase in internal and decrease in external HLC, which is interesting and indicates that further research should be carried out because no study has yet focused on such changes during breast cancer chemotherapy. Internal HLC correlates with health behaviors in the general population,[45] whereas the same has been found in a breast cancer survivors study.[46] The observed changes should be taken into consideration because an unhealthy lifestyle is a potential risk factor for cancer and noncancer mortality of women with breast cancer.[47,48] These changes could mean that participants will be more able to make healthier lifestyle decisions, which would reduce such mortality risks. For the dimension of powerful others, no effect was noted. This could be attributed to the fact that these patients, because of their disease status, socialize with many powerful others such as oncologists, nurses, and caregivers, who are usually their

family members. Moreover, the 2 primary researchers may have been considered as new powerful others who were partially responsible for their health status. Thus, the absence of changes in this dimension should not cause confusion.

In addition, conclusions cannot be drawn with regard to some other parameters that remained unaffected after the intervention. SRH and SWBS scores might underline solid beliefs and attitudes that were kept constant during the course of chemotherapy. The spiritual well-being of breast cancer patients was improved in one study through a 6-week spiritual therapy intervention.[49] Taking into account the above research and the absence of positive changes through our stress management and health promotion program, future studies should be directed toward such spiritually supportive therapy.

As regards the qualitative data following the intervention, self-reports of reduction in chemotherapy side effects with the program cannot be disregarded. Taking into account a recent study showing that women who had undergone breast cancer chemotherapy would risk a 38% chance of dying rather than experiencing grade III/IV nausea/vomiting for the rest of their lives,[50] the development of a program to decrease side effects should be viewed as necessary. Although these self-reports have a low future clinical implication value, they could provide researchers with the motivation to further look for reduction in side effects through stress management.

Two other limitations were the short duration of follow-up and the small sample size. In addition, most measures were carried out with the use of self-report questionnaires instead of biomarkers (eg, cortisol levels for stress), which could have been more reliable. Considering that there were no records of compliance with the program, adherence to some of the techniques and modifications cannot reveal possible associations with benefits assessed. Besides, characteristics that could mediate the program outcomes were not calculated. Moreover, the presentation of the beneficial effects from previous studies to the participants might be responsible for a favorable bias in answers. Finally, the control group received fewer sessions than the intervention group and also received them in conjunction with standard chemotherapy treatment, unlike the intervention group. Thus, apart from a difference in the number of sessions, there could also be one in the frame of mind of the control group participants when meeting with the research team. For these reasons, the differences between the 2 groups could pose some limitations to this study.

Conclusions

In conclusion, we state that the present program is a feasible one for stress management and health promotion in women undergoing breast cancer chemotherapy and could lead to several beneficial outcomes. However, it is as yet unclear whether this program, aiming at the patient's health promotion, may decrease future morbidity and hospitalization. Thus, a larger trial is necessary before suggesting that public health policy makers consider any possible cost-effective benefits and adopt it along with standard cancer treatment.

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Authors' Note

Konstantinos Syrigos and Christina Darviri contributed equally and share last authorship.

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