

TAKING CHARGE: A SELF-MANAGEMENT PROGRAM FOR WOMEN FOLLOWING BREAST CANCER TREATMENT

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SUMMARY

The purpose of the study was to develop and evaluate Taking CHARGE, a self-management intervention designed to facilitate successful transitions to survivorship after breast cancer treatment. The Taking CHARGE intervention involves a two-pronged approach building on self-regulation principles to (1) equip women with self-management skills to address concerns following breast cancer treatment, and (2) provide information about common survivorship topics. The program involved four intervention contacts, two small group meetings and two individualized telephone sessions, delivered by nurse/health educators. This paper focuses on the process evaluation findings from a preliminary test of the Taking CHARGE intervention conducted with 25 women, aged 34–66 years, completing breast cancer treatment, who were randomly assigned to the intervention group. The process evaluation was conducted to obtain systematic information about the relevance and usefulness of the self-regulation approach, informational aspects, and program delivery. The findings indicated that intervention group participants found the Taking CHARGE program to be timely, relevant, and to have high utility in dealing with concerns that exist following breast cancer treatment. The process evaluation findings provide early evidence of the usefulness of the Taking CHARGE intervention for successful transition to survivorship following breast cancer treatment. Copyright © 2005 John Wiley & Sons, Ltd.

INTRODUCTION

Women diagnosed with breast cancer represent one of the largest groups of cancer survivors comprising about 20% of the more than 10 million cancer survivors in the United States (1992 National Health Interview Survey, 1999). While considerable research and attention has been focused on the time of diagnosis, treatment initiation, and five-year survivorship, almost no attention has been paid to the period immediately following the completion of treatment when, for the first time, women with breast cancer are largely free from regular interactions with the health care system.

The purpose of the present study was to develop and test a self-management program, Taking CHARGE, designed to assist women to achieve successful transitions to survivorship following breast cancer treatment. The intervention was developed in response to two factors: (1) extensive research shows that women experience persistent physical, emotional, and social problems following breast cancer treatment; and (2) the dearth of programs available to meet these needs. This report describes the Taking CHARGE intervention and focuses on the process evaluation findings for women who received the intervention.

Persistent problems following breast cancer treatment

There is considerable evidence that women with breast cancer experience persistent physical, emotional, and social problems following treatment

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(Ell *et al.*, 1989; Ganz, *et al.*, 1996; Northouse, 1989). Common concerns include fear of recurrence, uncertainty about the future, and coming to terms with losses, changes in body image and life roles (Pelusi, 1997; Breaden, 1997; Hilton, 1988; Ferrell *et al.*, 1995; Dow *et al.*, 1996), as well as feeling abandoned by their health care professionals (1992 National Health Interview Survey, 1999; Ward *et al.*, 1992; Lethborg *et al.*, 2000). Moreover, women who are highly distressed during the early phase of illness report poorer long-term adjustment outcomes (Ell *et al.*, 1989; Maunsell *et al.*, 1992; Morris *et al.*, 1977; Schag, *et al.* 1993).

Physical symptoms are another ongoing concern for breast cancer survivors. Fatigue (Ferrell *et al.*, 1995; Ferrell *et al.*, 1997; Andrykowski *et al.*, 1998; Winningham *et al.*, 1994; Knobf, 1986; Graydon, 1994), recurrent pain and sensory discomfort in the surgical area (Baron *et al.*, 2000; Coscarelli-Shag *et al.*, 1993; Ferrell *et al.*, 1998), lymphedema (Petrek and Heelan, 1998), and hormonal changes that can cause menopausal symptoms such as hot flashes, night sweats, and vaginal dryness (Stein *et al.*, 2000; Bauer *et al.*, 2001; Ganz *et al.*, 1999) are among the most troubling symptoms following treatment.

Women must also strive to resume family, work, and social responsibilities (Leigh and Clark, 1998). Survivors report significant decreases in social support following treatment (Bloom, 1982; Northouse, 1988; Speigel *et al.*, 1989; Northouse *et al.*, 1998). Women have reported concerns about balancing their own needs with those of family, work, children, and their partner (Dunn and Steginga, 2000). Breast cancer survivors have also reported work difficulties including job loss, demotion, task modifications, changes in relations, and fears of being less productive (Rendle, 1997; Maunsell *et al.*, 1999).

Interventions for breast cancer survivors

Most interventions for women with breast cancer are geared to the period between diagnosis and the treatment decision or during treatment itself. Interventions have involved patient education (Devine and Westlake, 1995); improving coping skills; (Meyer and Mark, 1995); brief telephone therapy (Sandgren and McCaul, 2003); exercise interventions (Mock *et al.*, 2001); cognitive-behavioral stress management (Antoni *et al.*,

2001); and support groups (Helgeson *et al.*, 1999). Despite studies documenting problems (Rustøen and Begnum, 2000; Rendle, 1997; Keller, 1998; Polinsky, 1994) and expressed needs (Ferrell *et al.*, 1998; Luker *et al.*, 1996; Moadel *et al.*, 1999), few interventions have been designed to meet the needs of women as they adjust to survivorship following treatment.

The literature contains reports of a few interventions directed at breast cancer patients following treatment. One offered telephone cognitive-behavioral therapy and found no significant differences between the intervention and control groups. The researchers concluded that the treatment was 'weak' because it did not include an educational component and the graduate student therapists who delivered the intervention lacked sufficient oncology experience (Sandgren *et al.*, 2000). Another study tested the effects of a 6-week group psychosocial intervention versus a self-instructional module (Simpson *et al.*, 2001). Although psychological distress and symptoms decreased following the intervention, the findings were limited by poor accrual and 40% attrition.

Three other intervention studies have recently been reported. Marcus *et al.* (1998) described the development of a large randomized clinical trial to determine the benefits of a telephone-based, psychoeducational intervention on quality of life and other outcomes following completion of treatment for early stage breast cancer. Samarel *et al.* (1999) described the development of a 'resource kit' to facilitate adaptation to diagnosis, treatment, and recovery. Finally, Ganz *et al.* (2004) reported conducting a randomized clinical trial called the 'Moving Beyond Cancer' study testing psychoeducational interventions for women at the end of primary breast cancer treatment.

The Taking CHARGE intervention was developed to address the needs of women following breast cancer treatment using an innovative self-management approach. The intervention is unique because it: (1) is informed by social cognitive theory, particularly the principles of self-regulation; (2) offers women skill-building activities aimed at enhancing self-efficacy and improving self-regulatory behaviors; (3) provides information to address the physical, psychological, and social concerns that confront women in making transitions following breast cancer treatment; (4) allows each woman to work on a particular concern that is most relevant for her; and (5) incorporates both small group sessions and individually focused

telephone sessions to meet the documented needs of women, while being sensitive to their competing time demands.

Theoretical framework

The Taking CHARGE intervention builds on two theoretical frameworks: Mullan's (1985) stages of cancer survivorship and Bandura's (1986) social cognitive theory. Mullan proposed a three-stage survivorship continuum beginning with an acute or crisis stage, an extended or transitional stage, and a permanent survival stage. The Taking CHARGE intervention is directed at women in the extended survival stage and their transitional tasks.

The Taking CHARGE intervention also employs social cognitive theory. The program applies self-regulation principles to help breast cancer survivors to construct a useful understanding of the illness experience to guide self-care behaviors, develop and rehearse necessary management and coping skills, assess the effectiveness of their plan, and connect the experience and self-care strategies to individual lifestyle. Participants use self-regulation processes to prevent, identify, and resolve problems they confront in living with breast cancer and to gain mastery of necessary coping skills. This process has been successfully applied in an intervention for women with cardiac disease that was associated with positive effects on health-related quality of life, psychosocial and physical functioning, and symptom management (Janz *et al.*, 1999; Clark *et al.*, 2000).

Taking CHARGE structure and design

Taking CHARGE consisted of four intervention contacts made at two-week intervals over a seven-week period. An oncology nurse practitioner and a health educator trained in the Taking CHARGE process co-facilitated the program. The intervention consisted of two small group sessions and two individual telephone sessions. Content was the major criteria used to determine the session format. The content dealing with psychological well being (Session 1) and transitioning successfully to family, work, and social roles (Session 4) was considered especially appropriate for the small group format, which offered opportunities to share experiences and self-man-

agement strategies. Content related to managing symptoms (Session 2) and achieving functional wellness (Session 3) was delivered by telephone to tailor the sessions to each woman's unique experiences following treatment. This blended delivery system allowed participants to experience peer support in small group sessions and receive individualized education via telephone.

Each participant received a Taking CHARGE workbook that served as a 'road map' for each session and guided women through the steps in the self-regulation process and the breast cancer-specific content areas. Participants used the workbook to review key content covered in the group discussions and better prepare for the issues to be discussed during the telephone calls. The workbook was designed with the assistance of health media consultants to engage the participant's interest in specific activities related to each instructional session.

Each of the four sessions in the Taking CHARGE intervention served two purposes: (1) to teach steps in the self-regulation process, and (2) to address common concerns in breast cancer survivorship. Table 1 details the dual purposes and activities for each of the four sessions and reflects the content of each session in the participant's workbook. For clarity, the description below concentrates first on the self-regulation process across the four sessions and then focuses on the breast cancer-specific content offered in each session.

CHARGE is an acronym for the six steps in the self-regulation process: C—choose a concern, H—have the information, A—assess the situation, R—record the plan, G—gain confidence and insight, and, E—evaluate your progress. Accordingly, Taking CHARGE participants were taught to assess their perceived needs and monitor their own behavior and reactions to accurately assess concerns (Steps C, H, A). Participants then learned to identify a behavioral goal and develop a personalized strategic plan for reaching it (Steps R and G). Finally, Taking CHARGE emphasized the importance of evaluating the benefits of selected self-care activities and personal progress toward the goal (Step E). Importantly, women chose to work on one of the following concerns that were most relevant to their survivorship: stress, fatigue, physical activity, or personal relationships. Thus, although all participants received the same core content, women could select specific goals and identify needed skills based on their own concerns. Sample activities

Table 1. Taking CHARGE intervention framework

	Self-regulation content		Breast cancer survivorship content	
	Process steps	Sample activities	Themes	Sample activities
SESSION I Improving psychological well being Small group	<p><i>C step:</i> choose a concern:</p> <ul style="list-style-type: none"> ● stress management ● fatigue management ● physical activity ● personal relationships <p><i>H step:</i> have information</p>	<ul style="list-style-type: none"> ● Identify common areas of concern ● Select one personal concern to work on ● Use logs to record behavior ● Wear a pedometer to monitor distance walked 	<p>Sources of distress (e.g. worry, fear, loss, anger, and guilt)</p> <p>Identifying triggers</p> <p>Changes in relationships</p>	<ul style="list-style-type: none"> ● Share experiences of areas of distress ● Determine strengths and support systems ● Explore strategies and resources to deal with distress ● Use a Tracking Chart to examine feelings and reactions
SESSION II Dealing with symptoms and side-effects of treatment	<p><i>A step:</i> assess the situation</p>	<ul style="list-style-type: none"> ● Identify patterns of behavior from logs ● Identify barriers related to specific area of concern 	<p>Assess symptom experience</p> <p>Explore relevant management techniques</p>	<p><i>Menopause</i></p> <ul style="list-style-type: none"> ● List menopausal symptoms experienced ● Plan and use self-care strategies related to menopause
Telephone	<p><i>R step:</i> record a plan</p>	<ul style="list-style-type: none"> ● Identify a long and short-term goal ● Rate confidence in reaching goal ● Develop and record a plan ● Establish a reward for reaching the goal 	<p><i>Attention paid to</i></p> <ul style="list-style-type: none"> ● Menopause ● Fatigue ● Lymphedema 	<p><i>Fatigue</i></p> <ul style="list-style-type: none"> ● Identify types of fatigue with the Fatigue Scale and Diagram ● Emphasize usefulness of physical activities and attention-restoring experiences <p><i>Lymphedema</i></p> <ul style="list-style-type: none"> ● Determine if symptoms of lymphedema are present ● Review signs indicating need for medical attention

Table 1 (continued).

Self-regulation content		Breast cancer survivorship content		
	Process steps	Sample activities	Themes	
SESSION III Achieving functional wellness through healthy lifestyle Telephone	<i>G step</i> : gain confidence and insight	<ul style="list-style-type: none"> List insights reached over the last four weeks Rate confidence in continuing plan 	Regaining a sense of personal health in mind and body <i>Attention paid to</i> <ul style="list-style-type: none"> Body Image Sexuality Exercise Nutrition Mental restoration 	<ul style="list-style-type: none"> Identify body image or sexuality issues Complete a Physical Self-Assessment Review American Cancer Society's nutrition and cancer prevention guidelines Commit to one restorative activity Develop Personal Wellness Plan
	<i>E step</i> : evaluate your progress	<ul style="list-style-type: none"> Re-evaluate goals and alter plan if necessary Continue with present goals and plan 		
SESSION IV Strengthening personal and social relationships and resuming valued life roles Small group	<i>E step</i> : evaluate your progress (continued)	<ul style="list-style-type: none"> Complete a self contract Explore how self-regulation process can be adapted for new concerns 	Strengthening personal relationships Reestablishing life roles <i>Attention paid to:</i> <ul style="list-style-type: none"> Common challenges Realistic expectations Maintaining support Family and work-related issues 	<ul style="list-style-type: none"> Explore congruence between family and self-expectations Develop strategies to resume healthy relationships Use 'interactive communication tool' Share challenges of return to work Identify challenges in transition to survivorship Discuss strengths and resources to help in the journey Reaffirm new sense of self
	Review the Taking CHARGE steps			

that guided them through the steps of self-regulation included using a pedometer to monitor physical activity, recording behavior in observation logs, identifying relevant barriers, rating self-confidence in changing specific behaviors, and employing a self-contract (see Table 1). Applying the self-regulation steps to address one area of concern was intended to equip women with an approach that could be used in dealing with additional concerns over the course of breast cancer survivorship.

The survivorship content presented in the intervention sessions was derived from empirical studies and the experiences of the clinical researchers working with breast cancer patients. Session one, 'Enhancing Psychological Well-being', focused on reducing psychological distress and improving skills to enhance personal growth. The session included a discussion of sources of distress (e.g. fear of recurrence and intrusive thoughts about cancer) as well as sources of strength (e.g. positive coping strategies, finding meaning in illness). Participants shared their stories, heard the experiences of others, generated individual goals based on life values and priorities, and developed personalized self-care strategies for reducing emotional distress. Overall, the session was designed to improve psychological well-being, foster a sense of self-efficacy, and help inoculate against setbacks.

Session two concentrated on 'Managing Physical Symptoms and Side Effects' that arise following and often persist well beyond the end of treatment. The intervention uniformly addressed such common symptoms as fatigue, menopausal symptoms, and lymphedema. Insomnia, loss of concentration, changes in appearance and body image, and other symptoms were addressed. Self-assessment and self-monitoring of distressing symptoms and side effects was an important aspect of the program. Each woman developed a personal self-care plan to reduce severity or even eliminate identified symptoms and side effects.

The third session, 'Achieving Functional Wellness through a Healthy Lifestyle', emphasized exercise and nutrition, evidence-based natural restorative activities, and stress reduction strategies. Participants developed a personal wellness plan to improve overall physical and mental functioning and quality of life. In addition, an important component of the personal wellness plan included appropriate self-health monitoring guidelines for breast self-examination and medical

follow-ups for clinical breast examinations and mammography.

Session four concluded the intervention by 'Promoting Functional Adjustment in Family, Work, and Social Roles'. The session highlighted the importance of social support and ways to obtain needed support following treatment. Communication skills that ease interpersonal and social adjustments across life roles and settings were addressed. Women identified sources of support from family, friends, and local support groups. Discussion also centered on strategies and resources to facilitate a smooth return to work for women confronting that challenge.

METHODOLOGY

Evaluation design

The Taking CHARGE intervention was developed through an iterative process. First, quality of life researchers, medical and nursing oncology specialists, and breast cancer survivors provided expert review and content validation. Second, a pilot test involving 12 women who had recently completed their breast cancer treatment confirmed the feasibility of delivering the intervention. Finally, as a preliminary test of the intervention's effectiveness, a randomized clinical trial that included both process and outcome evaluations was conducted with women who had completed primary treatment for early stage (I or II) breast cancer. The process evaluation, completed only by participants randomly assigned to the intervention group, focused on the effectiveness of the program's structure and content, format of group and telephone sessions, and overall delivery. This report presents findings from the process evaluation conducted with women randomly assigned to the intervention group. The outcome evaluation involved a telephone-administered questionnaire of all participants at three time points: before the intervention, immediately following completion of the intervention, and three months following completion of the intervention. The telephone questionnaire included a number of generic and condition-specific measures addressing the specific study objectives and content areas. The outcome evaluation is not the focus of this article; outcome evaluation results will be presented in a forthcoming paper.

Sample and procedures

All study participants had to meet the following eligibility criteria: completed primary treatment for newly diagnosed, early Stage I or II breast cancer; 25 years of age or older; no history of cognitive impairment; no affective disorder within the previous year; no previous history of cancer; no terminal or debilitating illness; corrected hearing and vision; sufficient command of the English language to participate in the intervention and assessments; and, have a telephone. Participants were recruited from two types of clinical settings, an academic cancer treatment center and community oncology treatment clinics. The Institutional Review Boards of the participating institutions approved the study.

Eligible potential participants were identified through physicians and nurses in clinical settings and affiliated private physician practices. Recruitment occurred within one to four months following completion of chemotherapy or radiation. Baseline telephone interviews were completed within 30 days of enrollment. Following the baseline interview, subjects were stratified by chemotherapy treatment (Yes/No) and randomly assigned by strata either to the Taking CHARGE intervention or 'usual care' control group using a balanced block randomization procedure. Experimental subjects began the Taking CHARGE program within 30 days following completion of their baseline interview. Experimental group subjects completed the anonymous process evaluation questionnaire at the end of the fourth and final session.

An instructor's manual was developed to ensure that all nurse/health educators used standard instructional content and methods. Quality control of the intervention was assured by observation using a checklist of critical intervention behaviors, review of a sample of telephone interventions, and use of process assessment tools including checklists that documented the material delivered in each session.

Process evaluation measures

The process evaluation completed at the end of session four was designed to obtain systematic information from intervention group women about their participation in Taking CHARGE. Questions were posed to evaluate all aspects of the program including: self-management activities

(seven items); program content and materials, such as usefulness of the self-regulation approach, session contents, and workbook (10 items); program format and delivery, such as usefulness of group sessions and telephone sessions (seven items), and suggestions for additional topics to include in the intervention (10 items). The participants were instructed to respond yes/no to certain items and to rate others using a 5-point scale (for example, 1=not useful to 5=very useful). In addition, two open-ended questions probed which aspects of the program were most beneficial and which were least beneficial from the participant's perspective. A summary of process evaluation items with response categories is presented in the appendix.

Data analysis procedures

Descriptive statistics were used to examine responses related to level of participation in intervention activities, usefulness of the self-regulation approach, and an assessment of the program's content including breadth and depth of information provided, workbook and intervention materials, and perceived support in the group sessions.

RESULTS

Sample characteristics

A total of 49 women randomized to either the intervention ($n = 25$) or control group ($n = 24$) met the inclusion criteria. Three of the 25 women randomized to the intervention group did not complete the program for the following reasons: child became ill prior to start of program ($n = 1$); could not make the first session ($n = 1$); and did not want to continue after the first session ($n = 1$). Thus, 22 women completed the intervention, and their responses to the process evaluation are reported here.

Participants in the intervention group ranged in age from 34 to 66 years old ($M = 48$ years, $SD = 8$). The majority (76%) were currently married or living with a partner. Most were white (92%), and the majority were relatively well educated (48% had a college or advanced degree). Slightly more than one-third (36%) were working full time outside the home, 32% reported part-time

work and 32% reported being unemployed or retired. Only 8% reported a family income of less than \$30 000, while 40% reported a family income in the range of \$30 000 to \$69 000, and 52% reported a family income of \$70 000 or more. Based on post-surgical pathological staging, the majority (52%) had Stage II disease. The most common (46%) treatment was a combination of lumpectomy, radiation therapy and adjuvant chemotherapy. Overall, 79% of the sample were treated with some form of adjuvant chemotherapy. Women randomly assigned to the intervention group were similar in demographic and medical characteristics to those randomized to the control group.

Participation in self-management activities

In evaluating the Taking CHARGE process for improving self-management skills, 100% of the participants reported working on a personal problem or management concern (see Table 2). The most frequently selected areas were physical activity (50%), stress (27%) and fatigue (18%). All participants reported using the observation logs to monitor their patterns in relation to the selected concerns. Participants ranked the usefulness of such observations as high with an average ranking of 4.3 on a scale of 1 = not useful to 5 = very useful. One participant's comments reflected the importance of the logs in the self-regulation process. She said:

'It brought attention to areas in my daily/weekly routine that I was unaware of and helped answer the question of why am I so frustrated'.

All of the participants chose a specific short-term goal related to their personal concern (e.g. 'exercise

3 to 4 times per week,' 'make bedtime at 9 p.m.,' 'meditate every day'), and 91% developed a specific plan to reach the goal (see Table 2). The overwhelming majority (91%, $n = 20$) of subjects felt confident that they could reach their goals, with 59% ($n = 13$) stating that they were 'very' confident. In this respect, a participant commented on the self-management skill-building activities, 'Writing things down in this way gave me a whole new perspective. It helped with my self-confidence'.

Usefulness of taking CHARGE program

Participants ranked the usefulness of the Taking CHARGE problem-solving process high, with an average ranking of 4.1 on a scale of 1 (not useful) to 5 (very useful) (see Table 3). In evaluating the content in the Taking CHARGE program, subjects evaluated each of the four sessions on a scale of 1 (not useful) to 5 (very useful). Although participants ranked all the sessions as being useful, the session on improving psychological well-being was ranked highest ($M = 4.3$), followed closely by achieving functional wellness ($M = 4.1$) and dealing with symptoms and side effects ($M = 4.1$). Although found to be useful, strengthening personal and social relationships ($M = 3.8$) was ranked somewhat lower than the other content areas.

Table 3. Participants' ratings* of usefulness of Taking CHARGE program ($N = 22$)

	Mean	Min-Max
Self-management activities		
Problem solving approach	4.1	2-5
Program content areas		
Psychological well being	4.3	3-5
Dealing with symptoms and side effects	4.1	1-5
Achieving functional wellness	4.1	3-5
Strengthening personal/social relationships	3.8	2-5
Program delivery		
Group sessions	4.4	1-5
Telephone sessions	4.2	1-5
Nurse/Health Educator Support	4.4	1-5
Peer group support	4.1	1-5
Program materials		
Workbook	4.4	2-5

* Rating scale: 1 = not useful to 5 = very useful.

Table 2. Participants' use of self-management activities ($N = 22$)

	<i>N</i>	Percent (%)
Worked on a management concern	22	100
Type of Concern:		
Physical activity	11	50
Stress	6	27
Fatigue	4	18
Relationships	1	5
Used observation log	22	100
Chose a short-term goal	22	100
Developed a plan for goal	20	91
Had confidence in reaching goal	20	91

When asked what additional information not covered in the Taking CHARGE program would be helpful to women after completion of breast cancer treatment, the most frequently requested topics were nutrition (95%), risk for other cancers (86%), changes in body image (63%), and alternative/complementary therapies (56%). In addition, 55% thought that another session, preferably a group session should be added to the program.

Program delivery

Participants ranked both the group meetings and telephone sessions as being useful (group meetings: $M = 4.4$; telephone sessions: $M = 4.2$). In relation to the length of the sessions, 83% of the participants ranked both the group meetings and the telephone sessions as being 'just right'. Overall, 81% of the participants rated the length of the entire program as being just right, while 14% rated it as being too short, and only 5% thought it was too long.

In an effort to further determine optimal times for scheduling the group sessions, participants were asked about their preferences. The overwhelming majority of the participants (89%) preferred mornings or afternoons, while 11% preferred evenings. Fifty percent preferred that the group sessions be held on weekdays, while 44% preferred weekends and 6% said either time would work.

Participants reported receiving a high level of support from the nurse/health educator during the group and telephone intervention contacts, with a mean rating of 4.4 on a scale ranging from 1 = very little support to 5 = a lot of support (see Table 3). Similarly, participants were positive about the peer support they received through the small group sessions with a mean score of 4.1. One participant commented, 'Personal time in group was very rewarding! Every person I meet touches my life in some way. Thanks for bringing us together'.

In evaluating the program materials for Taking CHARGE, participants ranked the usefulness of the Taking CHARGE workbook as being high ($M = 4.4$) (see Table 3). A large majority (77%) reported having completed the workbook exercises and materials for the four sessions, and another 23% completed all materials for at least three of the sessions. Participants ranked the *amount* of information provided as 'just right' with an

average rank of 3.1 on a scale of 1 (too little) to 5 (too much). Similarly, participants ranked the *level* of the information as being 'just right' with a mean of 3.0 on a scale of 1 (too easy) to 5 (too difficult). A subject commented about the workbook:

'One of the greatest gifts I have received, it is my second bible. It has been so helpful, and I will be referring to it often. I feel the workbook was written just for me'.

Suggestions for improvement

Participants also were asked in an open-ended question, 'If you could change one thing in the program, what would it be?' Seven participants commented on the importance of the group sessions and stated that they preferred the group sessions to the telephone intervention contacts. Another participant stated about the group meetings: 'I would have liked even more women in the group. I think there is real value in that kind of exchange'. Not all subjects, however, were equally comfortable in the mix of women in the group setting as exemplified in this comment: 'The first group meeting was a little awkward. It might have been nice to have a closer 'match' to other members of the group, i.e. lumpectomy or mastectomy, age and whether they had children or not'. Other women indicated that they did not find any aspect of the program to be without benefit as exemplified in these comments, 'I enjoyed everything', and 'I honestly feel I benefited from the whole program'.

In addition to responding to the items in the process evaluation, a number of women made unsolicited comments about the program. The comments indicated that the program had been beneficial in helping these participants to confront concerns in a thoughtful and positive way with guidance from the nurse/health educator. One woman stated that what she found most beneficial was: 'The positive attitude of keeping going, even if you fail at something. The thought that you can re-evaluate and focus on a concern from another angle and succeed. The idea of not giving up'. Another woman commented on the importance of 'establishing goals, making a plan, monitoring progress, and doing all this work with a professional'.

DISCUSSION

This study describes a new, innovative program of care, called Taking CHARGE, which was developed for women who have completed treatment for breast cancer. Numerous studies have described the difficult process of adjustment that unfolds during the transition from completion of active treatment to the resumption of a 'new normal' everyday life (Ganz *et al.*, 1996; Pelusi, 1997; Ferrell *et al.*, 1995; Knobf, 1986; Lethborg *et al.*, 2000; Maunsell *et al.*, 1992). The Taking CHARGE program was developed to equip women with skills and information to deal with common concerns they were likely to confront during breast cancer survivorship.

The feasibility, relevance, and usefulness of the Taking CHARGE intervention was assessed using a process evaluation that was completed by women who were randomly assigned to receive the intervention. The findings obtained from the process evaluation indicated that participants randomly assigned to the intervention group found the program to be timely, relevant, and very useful in dealing with the psychosocial and physical concerns that exist after cancer treatment. Importantly, they indicated that the self-management skills gained from the program would be useful in dealing with future concerns that might arise during the extended period of breast cancer survivorship.

The Taking CHARGE intervention involves a very proactive process. It utilizes a self-regulation approach, based on social cognitive theory, to enhance women's self-management skills. Women responded very positively to this approach and actively participated in all aspects of the program. Each woman chose a specific concern to work on that had particular relevance to her and maintained a personal observation log in the area related to her concern. For example, women who chose to increase their physical activity recorded the number of miles they walked and the number of calories they burned using a pedometer for a seven-day period of time. Women found this approach very valuable because it allowed them to gain a better understanding of their own activity pattern in relationship to their particular area of concern (physical inactivity). Women also actively participated in setting short-term goals for themselves and developed plans to reach their goals. Although women worked fairly independently on their own area of concern, they

also reported that the guidance they received from the health care professional was very beneficial. Women reported that the health professional's support and encouragement enhanced their confidence in their ability to reach their goals. Overall, the participants evaluated the self-regulation process as very useful in helping them to deal with specific concerns as they resume their lives after breast cancer treatment.

One of the unique features of this self-regulation process was that it offered *choice*. Women were able to select an area to work on from four areas reported as potentially problematic in the breast cancer survivorship literature. As indicated on the process evaluation, not all women chose the same concern. This opportunity to select an area of concern appears to be an important asset of the program, which may have enhanced the relevance of the program for the participants. It is of note that the majority of women (50%) chose to work on increasing their physical activity. However, it is also of note that a number of women chose to work on two other concerns, reducing stress (27%) and managing fatigue (18%). The different preferences of these women highlight the importance of allowing women some element of choice regarding which area they wanted to work on. It was of interest that only a small number of women (5%) chose to work on the area of improving social relationships. Although the value of social support in adjusting to breast cancer has been reported in many studies (Bloom, 1982; Northouse, 1988; Spiegel *et al.*, 1989), a number of women in this study reported that their current level of support from family and friends was high, indicating perhaps that they had less need to work on this particular area. However, a few women did select this area, suggesting that a selection of options is important.

The informational aspect of the program addressed common concerns reported in the breast cancer literature. Based on the ratings obtained from the process evaluation in this sample of women randomly assigned to the intervention group, the content areas that focused on improving psychological well-being, achieving functional wellness, and dealing with symptoms and side effects were rated as the most useful. The high ratings in these areas by women in our study are consistent with the importance attributed to these informational areas in other studies with breast cancer survivors (Luker *et al.*, 1996; Ferrell *et al.*, 1998). These ratings also indicate that these are

key areas to include in future programs designed to assist women following the completion of breast cancer treatment. Although the content on strengthening personal and social relationships also was rated as useful, the relatively high support our participants had may have accounted for the somewhat lower rating this area received in comparison to the other areas. In addition, participants may have perceived the other areas of concern to be more salient and easier to address using the self-regulation process. When asked what new areas of content should be added to the program, nearly all participants wanted more information about nutrition after cancer treatment. Another sizeable group of women wanted more information added on body image changes and their risk for developing other kinds of cancers.

Participants also evaluated the delivery method of the Taking CHARGE intervention, which involved two small group meetings and two individual telephone sessions. Participants gave high ratings to the group and telephone sessions, suggesting that both components were important and that the blended delivery approach was a viable method for implementing the Taking CHARGE program. A particular strength of the blended approach was that it enabled participants to receive peer support from survivors in a similar situation (following the completion of breast cancer treatment) as well as individualized professional support from a health professional during a private telephone session. In regard to program length, most of the participants felt that the length of the program was just right, indicating that the brief four-session intervention was an appropriate length.

One aspect of the program delivery that was initially problematic was providing the group sessions at a time that worked with the various participants' schedules, a problem reported by other investigators as well (Simpson *et al.*, 2001). Although there was high interest in the group sessions, not all women were able to attend the group meetings, particularly if they lived at a distance from the health care setting. The program was initially offered during weekday evenings to accommodate women who may be working or who may have had childcare responsibilities during the day. However, this time was not workable for a number of women. When future participants were informed about the study, they were asked about their preferences for group meeting times if they were randomized to the

intervention. We offered one of three time options—evening, weekend, or daytime. The daytime and weekend options received the highest endorsement. To accommodate more women, we subsequently provided women with both a daytime and a weekend group option, which had a very positive effect on participation. In spite of these options, however, there were still a few women who were unable to attend the group sessions. To overcome this barrier, the Taking CHARGE intervention was pilot tested as four individualized one-to-one sessions given by telephone. Although this format eliminates the valuable group component, preliminary findings from our small sample that received the individually based program suggest that this delivery option warrants further testing.

In spite of the very positive findings from the process evaluation, a few limitations should be noted. First, the program was delivered to a small sample of participants and needs to be tested with a larger sample of breast cancer survivors. Second, the sample was primarily white and well educated. Thus, the program needs to be tested in a sample that is more diverse with regard to race and socioeconomic status.

Overall, the participants reported a strong interest in and positive response to the Taking CHARGE intervention. One participant expressed surprise that such a program did not previously exist. She stated:

'To think that there has been no such program before...how many women feel confusion and despair without this support. I do hope it will become a regular program much like cardiac aftercare'.

The Taking CHARGE program has the potential to serve as a model intervention for successful transition to survivorship following breast cancer treatment. The program needs to be further tested for efficacy in a larger randomized clinical trial involving more diverse populations of women completing breast cancer treatment. If proven effective, this program could be replicated in various settings using a range of formats, including individualized telephone counseling and computer assisted instruction. With further research and development, the Taking CHARGE program has the potential to fill a significant gap in supportive cancer care services to improve recovery and quality of life for survivors of breast cancer.

APPENDIX A: SUMMARY OF ITEMS IN TAKING CHARGE PROGRAM
PROCESS EVALUATION

The summary of items in taking CHARGE program process evaluation is given in the following table

Content of question stem	Response categories
<i>I. Self-management activities</i>	
Chose a management concern	Yes/no
Specific concern chosen	Open-ended
Filled out observation logs	Yes/no
Usefulness of observation logs	Not useful (1) to very useful (5)
Chose a short-term goal	Yes/no
Developed a plan to reach short-term goal	Yes/no/not sure
Confidence in reaching short-term goal	No confidence (1) to very confident (5)
<i>II. Program content and materials</i>	
Usefulness of problem-solving approach	Not useful (1) to very useful (5)
Usefulness of each of the four program sessions (4 total)	Not useful (1) to very useful (5)
Usefulness of workbook	Not useful (1) to very useful (5)
Number of workbook sessions completed	None (0) to All (4)
Amount of information provided	Too little (1) to too much (5)
Level of information provided	Too easy (1) to too difficult (5)
Amount of information completed	A small amount (1) to everything (5)
Desire for information and/or session on topics not covered (10 total)*	Yes/no
<i>III. Program format and delivery</i>	
Usefulness of group/telephone sessions	Not useful (1) to very useful (5)
Satisfaction with length of group/telephone sessions	Too short/just right/too long
Satisfaction with length of program	Too short/just right/too long
Amount of support from nurse/health educator	Very little (1) to a lot (5)
Amount of peer support received	Very little (1) to a lot (5)
Desire for an additional session	Yes/no/not sure
Preferred format for additional session	Group/phone
<i>IV. Suggestions for improving program</i>	
One recommended change for program	Open-ended
Most and least beneficial aspects of program	Open-ended

*Topics included nutrition, children's concerns/reactions, being single/new relationships, letting go, breast cancer disease processes, sleep concerns, genetic testing, alternative/complementary therapies, body image, cancer risk, and others (please specify).

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