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The purpose of this 4-year study is to determine the effects of a comprehensive coping strategy program (CCSP) on clinical outcomes and quality of life in breast cancer patients and their caregivers.

Because data have been collected for 6 months at the time of this report, preliminary findings are presented.

The purpose of this 6 months study was to compare descriptions of pain, psychological distress, fatigue, and perceived health status and burden of care in breast cancer patients and their primary caregivers (PCGs) who received ABMT and participated in a CCSP and ABMT breast cancer patients and their PCGs who did not receive the CCSP. A randomized controlled clinical trial design was used with 20 patients and their primary caregivers (PCGs) participating in the study (6 in the treatment group and 14 in the control group.) Data were collected 35 days (baseline) and two days before the ABMT after high dose chemotherapy had been given. The CCSP intervention was given to the treatment group 14 days before the ABMT. The results showed trends that support the use of the CCSP in the reduction of pain and anxiety. The CCSP group increased their ability to control pain and use of positive coping strategies.

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Fannie Gaston-Johansson
Principal Investigator's Signature

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INTRODUCTION

Autologous bone marrow transplantation (ABMT) consists of the administration of high-dose chemotherapy and in some cases, total radiation, followed by rescue with autologous, cryopreserved, bone marrow cells. This treatment regimen has become an established alternative treatment in a variety of malignant diseases including breast cancer[1]. While potentially life-saving, ABMT can be a traumatic procedure and can seriously impact the patient's quality of life (QOL). The often severe and unrelenting pain from the treatment regimen, medical procedures and persistent adverse physical side effects such as pain, fatigue and nausea and vomiting result in a critically ill and psychologically distressed patient. These symptoms in turn affects the patient's health status and QOL[2-3]. The patient's primary caregiver may also experience psychological distress, severe fatigue, increased burden of care, and a less than optimum QOL[4-9].

The overall purpose of this four year research project is to measure the effects of a comprehensive coping strategy program (CCSP) on pain, psychological distress, fatigue, perceived health status, burden of care, and QOL for breast cancer ABMT patients and their primary caregivers.

The specific purpose of this paper is to present preliminary data that describes pain, psychological distress, fatigue, perceived health status, coping , and burden of care in breast cancer patients who receive ABMT and participate in a CCSP and breast cancer patients who do not receive the CCSP.

LITERATURE REVIEW

ABMT Patients

Pain associated with ABMT is well documented and is related to either the conditioning regimen and/or the ABMT procedure itself. Painful side effects of ABMT include the following: mucositis, ulcerations, chemical cystitis which may be complicated by infectious processes; nausea and vomiting; abdominal ascites related to veno-occlusive disease and/or hemorrhage[2]. The ABMT procedure can cause pain through numerous invasive techniques such as bone marrow aspirations, spinal taps and Hickman Catheter placement. Rappaport[10] reported that anxiety and depression were the most common psychological reactions in patients post-ABMT.

Anxiety regarding painful procedures, strict isolation, and depression were universal reactions during and for several months following ABMT[11]. Gaston-Johansson and associates[5] found that ABMT patients had moderate anxiety and depression during hospitalization and at discharge with anxiety and depression reaching peak intensity 5 days post ABMT.

Jenkins and associates[12] found that 40% of ABMT patients, suffered from major depression at some stage during the transplant procedure. Case studies and anecdotal description suggest that strict isolation, medical procedures, and pain are frequent contributors to anxiety and depression in ABMT patients, with pain described as the most frequent factor[12]. Research documenting a positive relationship of pain to anxiety and depression in cancer patients is extensive[18,19].

About 33-76% of patients who undergo ABMT experience a high degree of fatigue[13]. Frequency and severity of pain, psychological distress and fatigue influences a patient's perceived health status, quality of life and length of hospital stay[14].

A patient's beliefs about his health status have been shown to be an important determinant of health outcomes[9]. The health status of ABMT patients vary. Some breast cancer ABMT patients leave the hospital within three weeks, while others stay 2-3 months. About 35% of patients utilize emergency room services and about 15-50% require one or more rehospitalization[20].

Primary Caregiver (PCG)

The PCG is the person identified by the patient as the significant other. The PCG is usually the single greatest support person for the patient during the transplant process and at other difficult times[16]. No studies to date have documented the PCG's psychological distress or negative outcomes related to care of the breast cancer ABMT patient, or how they cope with problems related to caregiving burden. Burdens which can contribute to this distress include the patient's medical regimen, the constant/multiple patient demands prior to, during and months/years after ABMT, possibly traveling long distances and displacement from home, friends and work, possibly living with a very ill person for a long time, and competing family/work responsibilities. There is some evidence that caregivers experience positive reactions[16]. However, most investigators suggest that caregivers[6] responsibilities have negative effects on the caregivers' quality of life. Caregivers frequently demonstrate poor health and severe fatigue, in addition to frustration, anxiety and depression.

Comprehensive Coping Strategy Program (CCSP)

The Gate-Control Theory of pain by Melzack and Wall[18] and the Stress, Coping and Adaptation Paradigm by Lazarus[19] provide the theoretical framework for this study. Pain is defined as a multi-dimensional sensory and affective experience associated with discomfort[18]. Coping is defined as constantly changing cognitive and behavioral efforts used to manage specific external and /or internal demands that are appraised as taxing or exceeding the resources of a person[19]. Positive coping strategies refer to internal thoughts and behaviors people use to manage their pain, or their emotional reactions to the pain and to reduce emotional distress. Catastrophizing, a negative coping strategy, is defined as a method of cognitive coping characterized by negative self-statements and thoughts about the future[20,21].

Previous research studies have shown that pain and emotional distress can be reduced in pain patients by providing, a) comprehensive coping strategy program (CCSP) which includes: preparatory information to increase control[21]; b) cognitive restructuring which includes positive coping statements and avoidance of catastrophizing,[21]; and; c) relaxation with guided imagery. A combination of these three components has been found to be the best overall coping intervention to reduce pain and stress rather than using each component separately[21]. However, no prospective or retrospective study was found in the scientific literature which included these three components in a unified coping strategy program to reduce pain and emotional distress and fatigue in breast cancer ABMT patients.

The following questions were asked in this preliminary descriptive study:

1. How do breast cancer patients who receive ABMT and participate in a CCSP describe pain,psychological distress, fatigue, and perceived health status compared to breast cancer patients who receive ABMT but not the CCSP?

2. How do primary caregivers, of breast cancer patients who receive ABMT and participate in a CCSP, describe their burden of care, and psychological distress compared to primary caregivers of ABMT patients who do not receive the CCSP?

METHODS & INSTRUMENTATION

Study Design

The study has a randomized controlled prospective clinical trial design with repeated treatment and measurements. Participants were randomized to two comparison groups for the purpose of measuring the effect of the proposed intervention, i.e. participation in a CCSP. Group I was composed of breast cancer patients and their PCGs who received the CCSP intervention. Group II included breast cancer patients and their PCGs who did not receive the CCSP. The initial preliminary effect of the CCSP was assessed by comparing differences in the means between the 2 groups in terms of the outcome measures.

Eligibility criteria for participation in the project were as follows: 1) scheduled to receive ABMT for breast cancer with stage III or IV; 2) able to speak and read English; 3) age $\geq$ 18 and; 4) able to give informed consent and identify a primary caregiver who is willing to participate in the study.

Patient Variables and Instruments

Socio-demographic and Background Variables

The information about demographic and background variables was collected on a standardized form and included the following information: age; race/ethnicity; marital status; educational level; religion and household income; employment status; and whether the subjects lived alone or with another person.

Pain Intensity and Quality

The Pain-O-Meter® (POM) is a hard white plastic tool which measures 8 inches long, 2 inches wide and 1 inch thick. It is light weighted and can easily be held by the subject. A list of 15 sensory and 11 affective pain descriptors are located on the front side of the POM and a 100 mm visual analogue scale with a moveable marker is located on the back side of the POM (POM-VAS). An intensity value (from a low of one to a high of five) is pre-determined for each sensory and affective word located on front of the POM. A maximum score can be obtained for the sensory component of pain and for the affective component.

A total score can be obtained by adding the sensory and affective scores. Test-retest reliability of the POM has been demonstrated as well as criterion related[24] and construct validity[22-26].

Psychological Distress

a) Anxiety. The State-Trait Anxiety Inventory (STAI) was used as one measure of psychological distress. The STAI consists of two separate self-report scales for measuring state and trait anxiety[27]. State anxiety is a transitory emotional response to a stressful situation. Trait anxiety reflects a stable predisposition to anxiety as determined by a personality pattern. Respondents rate themselves in relationship to the statement on a Likert scale from 1 to 4. The total score is the sum of all 20 responses and ranges from a minimum score of 20-39 (low anxiety), 40-59 (moderate anxiety), to a maximum score of 60-80 (high anxiety). Test-retest reliability and validity have been demonstrated for the STAI[27]. **b)** Depression: Beck's Depression Inventory (BDI) was also used to measure psychological distress. The BDI consists of 21 items that describe particular symptoms of depression[28]. Subjects respond to a Likert-type scale by rating each item 0 (no symptom) to 3 (severe or persistent presence of the symptom). Scores ranging from 0 to 9 are normal, 10 to 15 mild depression, 16 to 23 moderate depression, and 24 to 63 severe depression. The total score (range 0 to 63) is obtained by summing the 21 responses. Test-retest correlations of the BDI ranged from .60 to .90 in nonpsychiatric patients[28].

Fatigue

The Piper Fatigue Scale (PFS) was used to measure fatigue. This scale was designed to measure fatigue as a multidimensional phenomenon, defined as "a subjective feeling of tiredness, influenced by circadian rhythm, and other factors varying in duration, unpleasantness, and intensity"[29]. The scale consists of 41 horizontal 100 mm VAS items measuring four dimensions of subjective fatigue (temporal dimension, intensity/severity dimension, affective dimension, and sensory dimension.) A total fatigue score is calculated by summing the four scores and dividing by four[29].

Perceived Health Status

The Short-Form Health Survey (HS)[30] was used to measure perceived health status. The 20-item survey assesses physical functioning (6 items), role functioning (2 items), social functioning (1 item), mental health (5 items), health perception (5 items) and pain (1 item)[30]. Reliability[30] and construct validity has been demonstrated for the HS.

Coping strategies

The Coping Strategy Questionnaire (CSQ), developed by Keefe[20], will be used to assess a person's use of pain coping strategies. The categories of coping strategies assessed by this measure include: (1) diverting attention, (2) reinterpreting pain sensations, (3) ignoring pain sensations, (4) praying and hoping, (5) catastrophizing, and (6) increasing activity level. For each category of coping strategies there are 6 items on the CSQ with scores ranging from 0 to 36. Each item is rated on a 7 point scale to indicate how often that

strategy is used to cope with pain (0 = never, 3 = sometimes, and 6 = always). The CSQ also includes 2 items which measure overall effectiveness of those strategies used by asking the subjects to rate on a 7-point scale (with scores ranging from 0 to 6) how much control they have over the pain, and how much they are able to decrease their pain[20]. Reliability and construct validity have been demonstrated for the CSQ[56-64].

Burden of Care

Burden of care (BOC) was assessed using the Measurement of Objective Burden (MOB) and the Measurement of Subjective Burden (MSB) scales developed by Montgomery, Gonyea and Hooyman[31]. The MOB is a 9-item, 5-point scale ranging from (1), " a lot more or better", to (5), "a lot less or worse", designed to assess the extent to which caregiving behaviors have changed the caregiver's lives in nine areas: time for oneself; privacy; money; personal freedom; energy; recreational/social activities; vocational activities; relationships with other family members; and health. The MSB is a 13-item, 5-point scale from (1) "rarely or never" to (5) "most of the time", designed to assess attitudes toward or emotional reactions to the caregiving experience. Items for the MSB were adapted from the 29-item inventory relating to attitudes and feelings about caregiving developed by Zarit and associates[32]. Reported alpha was .85 for the MOB scale and .86 for the MSB scale[31].

CCSP Intervention

Purposes

The purposes of the CCSP are to: a) teach the patient and PCG how to decrease and control pain and discomfort; b) enhance the coping ability of the patient and PCG by teaching them to recognize distorted thinking, and how to use positive coping self-statements and; c) teach the patient and PCG how to use relaxation with imagery. The goal of the CCSP is to reduce pain, psychological distress, and reduce fatigue that is known to be intensified by pain and psychological distress. A decrease in these symptoms is expected to positively influence the subjects perceived health status and QOL. A detailed description of the CCSP is in the Appendix A.

Data Collection Procedure and Administration of CCSP

This 4 year study has been in effect for 11 months and data have been collected over a period of eight months. According to the study protocol, data are to be collected at 7 different time points at: a) baseline before the patient is hospitalized; b) 2 day before the ABMT; c) 7, and 20 days following the ABMT during hospitalization and; d) 3, 6 and 12 months following hospitalization. It takes about one year and 2 months for a complete set of data to be collected for each subject.

Baseline data were collected by the clinical nurse specialist -35 days of the ABMT. Two weeks prior to the ABMT (ABMT day -14), the CCSP intervention was taught to group I (treatment group) by a social worker experienced in teaching patients to use coping strategies and relaxation techniques. Group I (treatment group) was instructed to practice the CCSP daily as well as before stressful situations and to measure relaxation prior to and

following CCSP. The subjects in Group I were also instructed to record the number of times they practice the CCSP in a diary. The CCSP was reinforced with each patient in the patient's room by the research nurse participating in the project on days -8 and -2 before the ABMT. Data were collected by a research assistant who administered the Pain-O-Meter® and standardized questionnaires to all subjects (patients and their PCG) in groups I & II (control) during the patient's hospitalization. Data were collected on day -2 before the ABMT in the patient's room.

A subset of data collected at baseline and two days prior to the ABMT was collected in this study. Thus far, 20 patients and 20 primary caregivers have entered the study (six patients and their caregivers have been randomly assigned to the CCSP treatment group and 14 to the control group). A random sample of 6 subjects from the control group were selected to be presented with the 6 subjects in the treatment group.

Statistical Analysis

Descriptive statistics were used to analyze the data.

RESULTS

In reporting the preliminary results from this study, consideration has been given to the fact that the results are influenced by a limited sample size. As can be seen in Table I, there were a total of 20 patients and 20 primary caregivers (PCG) participating in the study. Only 6 patients and 6 PCG's were randomized to the treatment group. Fourteen were in the control group.

The demographic characteristics of the sample are presented in table I for the patients and their primary caregivers. The majority of the subjects were professionals with incomes - $\geq$ $50,000. They were Caucasians, married, with a college degree or some college, living with their spouses, and actively employed. The mean age of the patients was 40, and 46 for the primary caregivers.

ABMT Patients

Data are presented for treatment and control groups at baseline and ABMT day -2. Table II shows that pain decreased and relaxation increased after the reinforcement of the CCSP in the patients. Relaxation also increased after the reinforcement of the CCSP in the PCGs.

The means standard deviations for pain, psychological distress and coping were measured at baseline and two days before the ABMT after high dose chemotherapy had been given (Table III). In as much as the trends of the reported data are in the desired direction, the CCSP appears to be a promising treatment strategy. Patients receiving the CCSP showed lower scores in their pain and psychological distress (anxiety) and an increase in their coping ability from baseline to ABMT day -2. The treatment group showed an increase in five of the seven dimensions of coping (Table III), and an increase in their ability to control pain.

The improvements among the CCSP subjects were greater than those of the controls. The statistical significance of the increases have not been determined because of the sample

size.

The control group in contrast to the CCSP group, reported a very slight decrease in pain, an increase in their level of anxiety, and ability to control pain. The control group also reported a decrease in the use of five of the seven positive coping strategies (Tables III & IV).

Both the group receiving the CCSP and the control group reported an increase in all the sub-domains of fatigue between baseline and day -2 for ABMT (Table IV). Conversely, both of the groups reported a decrease in their health status from baseline to ABMT -2, as measured by each of the sub-constructs (Table IV). Figures 1 - 4 are graphic presentations of pain, ability to control pain, and anxiety for the CCSP group and comparison group.

Primary Caregiver (PCG)

Primary caregivers of both CCSP and control groups reported low anxiety levels at baseline and Day -2 ABMT. The CCSP group reported a mean anxiety score of 37.7 (SD = 11.4) at baseline and 37.0 (SD = 14.2) at Day -2 ABMT. The control group reported a mean anxiety score of 36.0 (SD = 9.5) at baseline and 35.6 (SD = 5.9) at Day -2 ABMT. All these scores are considered low anxiety.

Although small, PCGs of CCSP patients reported decreased Burden of Care (BOC), both for the objective and subjective levels. PCGs of the control group reported a minor increase in the objective burden of care and a decrease in the subjective BOC. The increase or decrease in the BOC reflects the difference between baseline and Day -2 ABMT time periods (Table IV).

DISCUSSION

In interpreting our findings from these preliminary analyses, several cautions need to be kept in mind. A comparison of results between baseline data and day -2 from ABMT may not be appropriate for several of the outcomes reported here. Although the time difference between baseline (day -35) and the first follow-up (day -2) was more than a month, the time period between the start of the intervention (day -14) and the first follow up may not have been adequate to show a desired improvement in such constructs as depression. The limited sample size at the time of reporting does not allow us to control for intervening factors such as demographic factors, severity of illness, degree of treatment and pathophysiological status at baseline, which may have high influence on the outcomes. The intervention is proposed to have indirect effect (and therefore could take longer time periods) on outcomes such as fatigue and overall health status. Consequently, the direct impact of CCSP, although at a univariate level, is seen as an improvement on pain, control of pain, anxiety state and several components of coping among the patients who received CCSP, but not among the control group. The data on fatigue and health status do not show any improvement at the first follow-up in both groups, possibly due to the indirect and long term impact. Similarly the catastrophizing component of coping does not show any improvement, possibly due to the fact that none of these patients had received the ABMT at the first follow-up. It is more likely that these patients are reporting higher scores on the catastrophizing component as they approach closer to the BMT data. The small improvement in the catastrophizing component reported by the comparison group could be

influenced by the high inter-observation variability (as noted from the high standard deviation).

Thus far, the preliminary descriptive results appear to be promising and in line with the major outcomes expected from this study.

Conclusion

Although the sample size is small, and this report is being made for two points in time regarding the data collection, there is a trend in the expected direction by our constructs. The fact that constructs such as patients' pain, control of pain, relaxation, the use of coping self-statements and praying show changes in the expected direction, lends support of the influence of the CCSP and to the patients' abilities to use the CCSP. Conceptually, we would expect to see a decrease in pain and anxiety, a trend that is found in the CCSP patient data but not among the control group. Limited sample size and time for data collection at this reporting phase, does not permit us to draw conclusions.

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Table I Socio-Demographic Characteristics of Patients and Primary Caregivers Receiving CCSP and Their Controls

	Patients		Primary Caregivers	
Variables	Treatment	Control	Treatment	Control
Age	41 ± 7	45 ± 9	41 ± 8	47 ± 9
Gender				
Female	6	14	2	3
Male			4	9
Race				
Caucasian	6	13	6	10
African-American		1		2
Marital Status				
Married	4	12	6	12
Single	1	2	1	
Divorced	1			
Education				
High School	2	3	1	2
Some College	1	4	1	3
College Graduate	2	3	2	4
College Degree	1	4	2	5
Religion				
Catholic	1	3	1	4
Protestant	3	6	4	4
Jewish	1	2	1	
Other	1	2		3
None		1		1
Lives with				
Spouse	4	11	6	10
Significant Other				
Child				
Parent				
Self	1	3		2

(Table I is continued on the next page)

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Variables	Patients		Primary Caregivers	
	Treatment	Control	Treatment	Control
Work				
Full-time	3	8	5	9
Part-time	2	1		1
Unemployed resigned		1		1
Unemployed disability	1	1	1	
Other		3		
Occupation				
Professional	1	7	5	7
Technical				2
Retired		4		1
Other	4	3	1	2
Income				
< $20,000	1	1		
$20,000 - $29,999			1	1
$30,000 - $39,999				
$40,000 - $49,999	1	1		2
≥ $50,000	2	9	5	9

Table II Mean and Standard Deviations for Pain Intensity and Relaxation for CCSP patients and their PCGs

ABMT Day	Variable	PATIENTS				PCGs			
		Before		After		Before		After	
		$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD
-14	Pain	1.15	3.07	0.72	1.04				
	Relaxation	7.83	2.75	9.32	0.55	7.15	2.76	9.55	0.21
- 8	Pain	3.33	4.54	2.6	4.08				
	Relaxation	6.83	1.47	8.8	1.31	6.85	3.04	8.85	1.48
- 2	Pain	3.76	3.70	4.07	5.04				
	Relaxation	4.43	2.05	4.30	4.31	6.20	0	7.0	0.28

Table III Differences Between Baseline and Day -2 from ABMT on Pain, Psychological Distress and Coping Among Patients Receiving CCSP and Their Controls.

		Baseline		Day -2		Difference	
Variable		Mean	SD	Mean	SD	Mean	SD
Pain	Tx	4.50	1.37	3.17	1.17	-1.33	1.75
	C	4.40	1.80	4.00	1.41	-0.40	2.19
Ability to Control Pain	Tx	64.83	36.29	68.83	26.80	4.00	26.12
	C	94.36	16.91	79.67	15.36	-14.67	18.46
State Anxiety	Tx	38.00	11.33	37.67	4.94	-0.33	6.41
	C	31.20	19.26	39.00	8.72	7.80	9.81
Depression	Tx	9.67	2.50	13.93	4.12	4.27	4.37
	C	4.45	4.41	6.84	4.41	1.39	4.41
Coping							
Ignoring Pain	Tx	11.33	5.71	9.17	5.85	-2.17	4.58
	C	14.00	5.10	10.80	4.82	-3.20	5.72
Coping Self-Statements	Tx	19.83	2.71	20.00	3.74	0.17	3.66
	C	23.40	4.13	18.20	5.40	-5.20	2.86
Reinterpreting Pain	Tx	6.00	5.89	6.83	4.88	0.83	4.45
Pain Sensations	C	6.80	7.39	7.20	6.26	0.40	8.50
Diverting Attention	Tx	22.66	5.08	23.50	6.44	0.83	4.07
	C	21.20	8.83	16.80	5.76	-4.40	11.91
Praying & Hoping	Tx	20.33	8.21	25.67	8.07	5.33	4.32
	C	12.00	6.53	15.20	6.53	3.20	6.53
Pain Behavior	Tx	17.50	7.34	17.67	6.41	0.17	5.71
	C	19.60	5.43	17.40	6.43	-2.20	4.44
Catastrophizing	Tx	4.16	3.18	6.83	3.06	2.67	3.14
	C	3.60	4.35	3.40	4.98	-0.20	3.83

Tx = Treatment Group
C = Control Group

Table IV Differences Between Baseline and Day -2 from ABMT on Fatigue and Health Status Among Patients Receiving CCSP and Their Controls

		Baseline		Day -2		Difference	
Variable		Mean	SD	Mean	SD	Mean	SD
Fatigue							
Temporal	Tx	10.65	10.89	52.89	18.56	42.24	13.03
	C	18.90	28.71	52.73	14.49	33.83	42.94
Intensity/ Severity	Tx	7.50	7.84	56.36	15.58	48.85	9.07
	C	4.65	17.27	28.01	14.10	23.36	20.44
Affective	Tx	23.96	27.35	56.07	19.27	32.13	29.70
	C	7.43	30.08	50.69	31.26	43.26	28.90
Sensory	Tx	29.65	16.34	56.04	19.27	26.39	17.78
	C	17.88	19.20	54.98	10.46	37.10	27.95
Total	Tx	17.94	13.71	55.34	13.07	37.40	12.21
	C	14.49	19.26	46.60	12.92	32.11	26.90
Health Status							
Physical Functioning	Tx	3.16	2.48	2.83	2.79	-0.33	3.27
	C	4.40	0.91	4.40	0.89	0.50	1.00
Role Functioning	Tx	0.66	1.03	0.50	0.84	-0.17	0.98
	C	1.00	0.84	0.80	0.84	-0.20	0.84
Social Functioning	Tx	4.66	1.86	4.17	1.17	-0.50	1.05
	C	4.40	1.30	5.20	1.30	0.80	1.30
Mental Health	Tx	22.66	5.20	22.17	2.64	-0.50	4.18
	C	24.60	1.91	24.80	1.92	0.20	1.92
Health Perception	Tx	16.50	4.80	14.17	5.56	-2.33	3.86
	C	17.20	6.50	15.60	6.19	-0.60	6.91

Tx = Treatment Group
C = Control Group

FIGURE 1

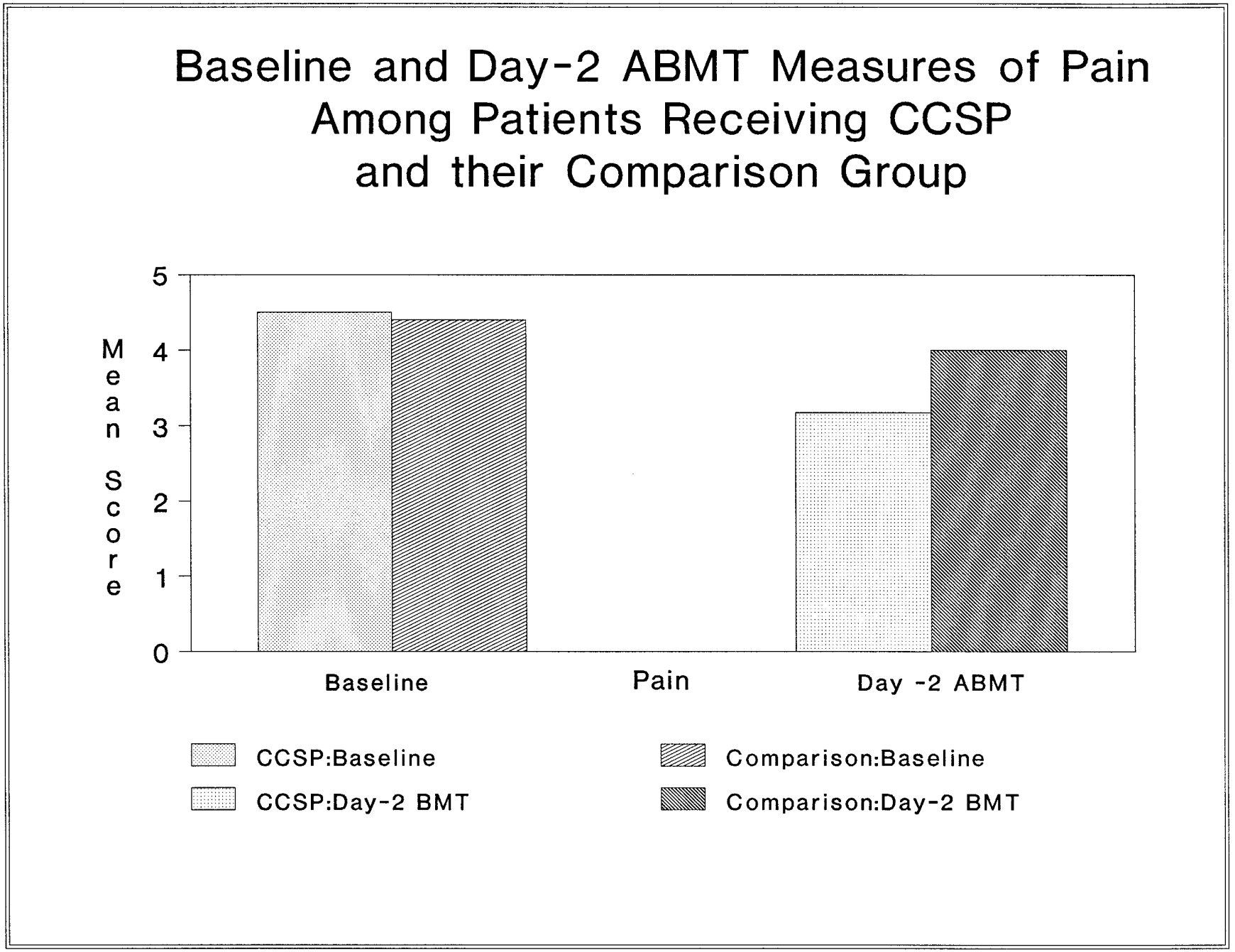

Baseline and Day-2 ABMT Measures of Pain
Among Patients Receiving CCSP
and their Comparison Group
Mean Score
5
4
3
2
1
0
Baseline
Pain
Day -2 ABMT
CCSP:Baseline
CCSP:Day-2 BMT
Comparison:Baseline
Comparison:Day-2 BMT

FIGURE 2

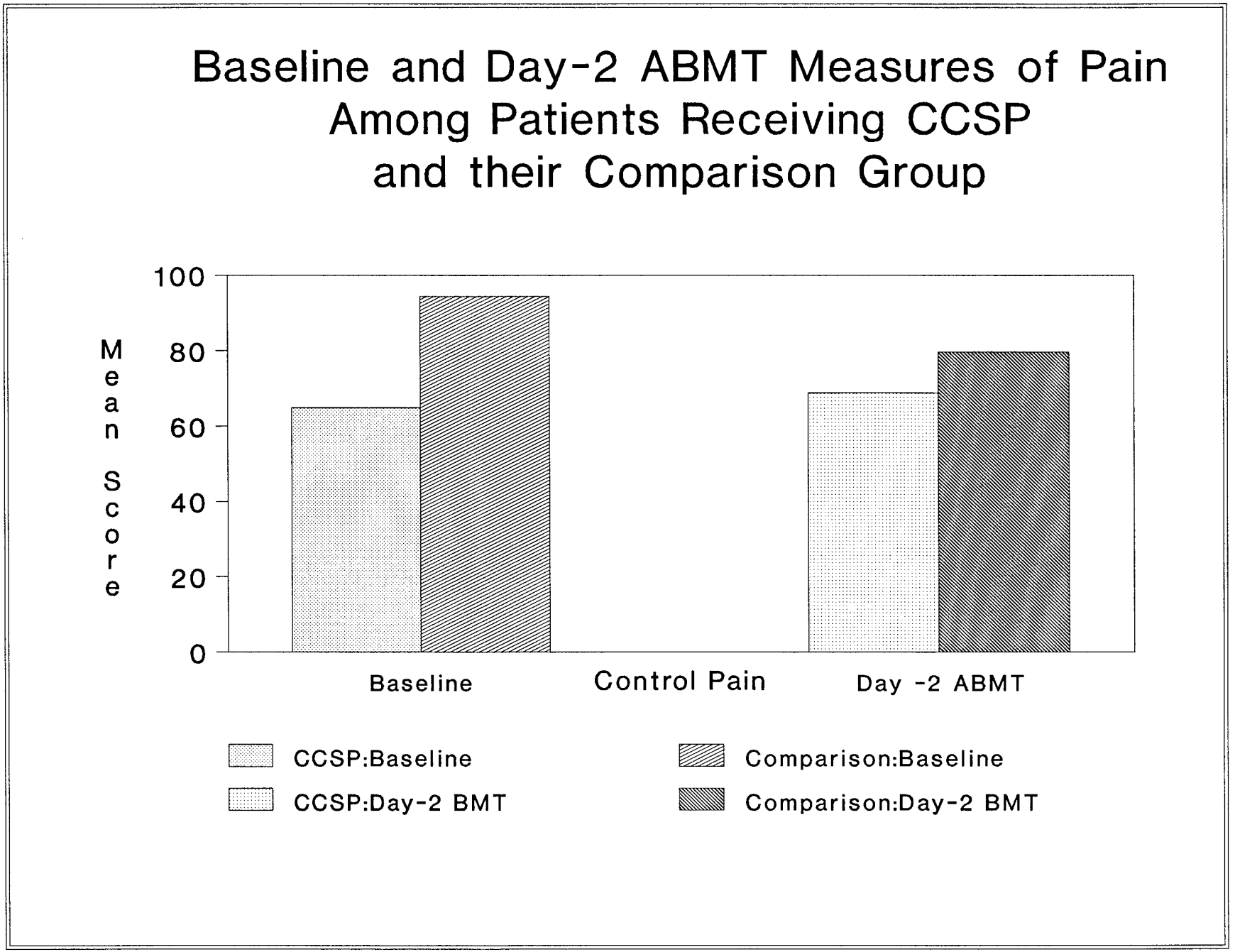
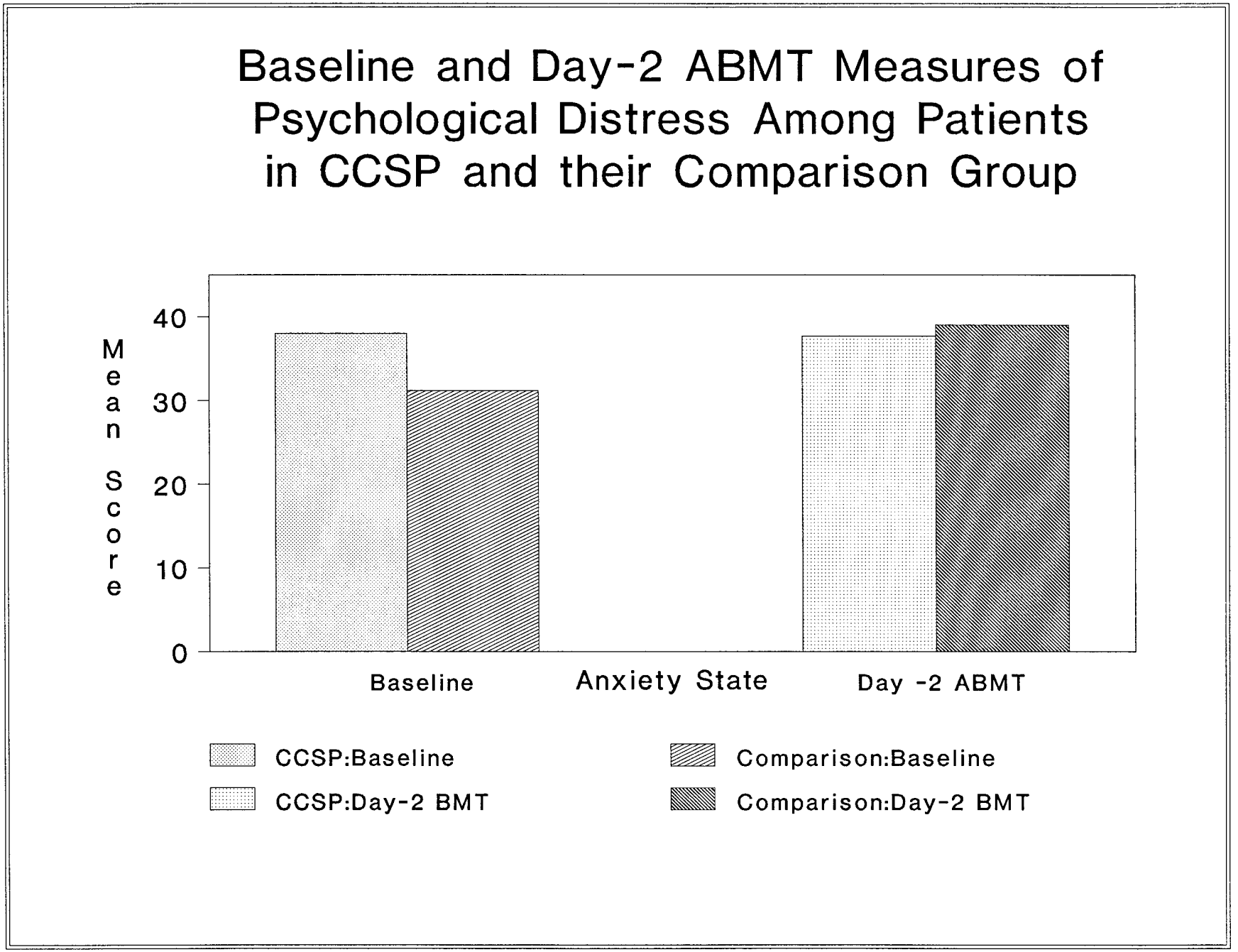

Baseline and Day-2 ABMT Measures of Pain Among Patients Receiving CCSP and their Comparison Group
Mean Score
100
80
60
40
20
0
Baseline
Control Pain
Day -2 ABMT
CCSP:Baseline
CCSP:Day-2 BMT
Comparison:Baseline
Comparison:Day-2 BMT

FIGURE 3


Baseline and Day-2 ABMT Measures of Psychological Distress Among Patients in CCSP and their Comparison Group
Mean Score
40
30
20
10
0
Baseline
Anxiety State
Day -2 ABMT
CCSP:Baseline
CCSP:Day-2 BMT
Comparison:Baseline
Comparison:Day-2 BMT

Presentation: A variety of teaching strategies are used to present the CCSP in order to help maintain breast cancer ABMT patient and PCG interest. Patients, particularly in clinical settings, are likely to experience a range of physical and psychological factors, such as pain, fatigue and anxiety resulting from high stress, which compete with the educator for their interest levels. Consideration was also given to providing the best match between specific content areas and the most appropriate teaching. Oral communication (lecture) has been found most effective in establishing rapport and in teaching new knowledge such as preparatory information, while slide tapes are especially beneficial for abstract concepts. Videotapes are most effective in situations where learning step-by-step procedures with movement is required, such as relaxation techniques with guided imagery. A conference/treatment room is used to present the CCSP. This setting has comfortable chairs and adequate space to practice relaxation. The setting is also appropriate for presenting educational materials.

Preparatory Information: The purposes of the CCSP are presented by the instructor using an overhead. A schematic drawing of the symptoms (pain, psychological distress, and fatigue) that patients are known to experience is presented. The instructor reviews the overhead pointing out the relationship among the different symptoms and how they can influence each other. The instructor summarizes the information by stressing that adequate control of pain can lead to decreased psychological distress and a decrease in physical symptoms other than fatigue. The subjects are told that the information presented is based on the experiences of patients who have successfully undergone ABMT. Handouts that cover appropriate information are reviewed and given to the participants: 1) "Ways in Which You Can Participate in Reducing Pain & Psychological Distress, and; 2) "Some General Ways To Increase Control". The above information is presented by the instructor using simple terminology and principles of learning. In order to make sure that the content is presented in a standardized manner, a detailed script and specific overheads are used by the instructor to present this material.

Treatment of Pain: Theoretical Considerations: This part of the CCSP is a slide presentation with an accompanying tape. Interaction between the instructor and the participants is also encouraged. Information covered include the following topics: definition of pain; the three components of pain; a brief explanation of the Gate Control Theory and; theoretical reasons why increasing control, through use of coping self-statements and relaxation with imagery can relieve pain and emotional distress. A handout, titled "Ways in Which You Can Participate In Reducing Pain" is reviewed by the instructor and given to the participants at the end of the session. Colorful slides of simple pictures, that symbolize neuro-physiological structures are used when the Gate Control Theory is presented.

Cognitive Restructuring: This segment of the CCSP is also a slide presentation with accompanying tape. This information focuses on the avoidance of catastrophizing, distorted thinking and the use of positive coping self-statements. Cognitive restructuring is directed at modifying thought processes in order to lessen negative sensations and psychological distress. The subjects are taught to conduct an internal dialogue with themselves which directs and refocuses their attention and thinking. This includes descriptions of unproductive catastrophizing statements made by people experiencing discomfort and distress, and then alternatives that may prove more useful in coping. This includes statements such as "I feel relaxed", "I am in control and can handle

this situation" and "I know any discomfort I may feel won't last forever". Two handouts, titled "15 Styles of Distorted Thinking to Avoid", and "15 Positive Coping Self-Statements," will be reviewed by the instructor and given to the participants.

Relaxation With Imagery: This part of the CCSP is presented on video-tape in a participant modeling format in which each component of relaxation will be briefly presented, described and demonstrated. The treatment includes a brief progressive muscle relaxation procedure with tense-release cycles being used with specific muscle groups (face, neck and shoulders, stomach and chest, arms and legs). Following these cycles, cue-controlled relaxation will be used involving deep breathing and saying the word "relax" to begin to develop an association between a state of relaxation and these cues. With practice, the cues can then be used to achieve a state of relaxation in a much shorter period of time. Imagery is introduced into the relaxation exercise and participants are permitted to choose the imaginary scene. At the end of the session, the instructor reviews two handouts and gives them to the participants. The handouts are: "Learning and Using Relaxation Therapy" and "Benefits of Relaxation Therapy". The instructor will also give the patient and PCG a small hand-held audiotape recorder (Walkman) with two sets of ear phones and an audiotape. The purpose of the tape is to guide the participants in active participation in the relaxation exercise. The participants are instructed to review all handouts and to practice the relaxation exercise, using the 15 minute audiotape at least every day and prior to stressful events. The subjects are instructed how to review the handouts and record their use of the audiotape in a diary.

Reinforcement of CCSP: The reinforcement of the CCSP includes: review of the patients and PCGs diaries, responding to any questions that the subjects have concerning the CCSP, measuring relaxation prior to and post reinforcement of the CCSP, reviewing all handouts with the subjects; and having the subjects listen to the 15 minute audiotape with the relaxation exercise with imagery. Reinforcement of the CCSP takes about 30 minutes.