CHAPTER 5
DISCUSSION

This non equivalent control group quasi-experimental study to assess the impact of two selected complementary therapies (Relaxation & Foot Massage) on the quality of life of Breast Cancer patients was undertaken with the major objective to reduce anxiety and depression of those subjects undergoing radiation to the chest wall and drainage areas thereby to improve their quality of life by the application of either of the two complementary therapies (i) Simple Rhythmic Breathing Relaxation (R Group) and (ii) Foot Massage (FM Group). The anxiety and depression were measured by HADS and Quality of Life by QOL-BC. The study also aimed at the determination of comparative effectiveness of the two interventions compared to the non-interventional group (Control). The findings of the study have been discussed with reference to the objectives and the hypotheses framed for the present study and with the findings of other studies.

GENERAL CHARACTERISTICS

There are many studies (Ferrell, et.al, 1996; Dow, 2000; Ferrans (1994); Mast, 1998) indicating that breast cancer is more prevalent among women aged 50 and above. According to the Hospital Cancer Registry (1998) of RCC, Trivandrum, the mean age of the 945 (27.2%) breast cancer cases was 48.6 years. North house (1994) pointed out that an inverse relationship between emotional distress and age is not consistent across the few available studies examining these factors. Age alone is rarely the most significant indicator of women’s psychological adjustment to breast cancer. In the present study, the age of the subjects ranged from 30-69 with the maximum in 40-49 age group with a mean age of 47 years.

Among the subjects studied, 49 % were Hindus followed by 39% Christians and the remaining 12% Muslims. Thus there was adequate representation of various religious sections in the present study. In the
present study, 85.6% of the subjects were ‘married’, 7.7% ‘widowed’ and the remaining 6.7% ‘never married’. The percentage of ‘never married’ women, in the community, may be very few, if the age group 30-69 is taken into account. So the finding is in conformity with the reported increased incidence of breast cancer among ‘never married’ women. Out of the 90 women studied, 33% had college level education, 28.9% had secondary school/above level of education and the remaining 38% only below secondary school education. Thus the study group is fairly represented by various educational groups. Every 3 out of 4 women were housewives and about 50 per cent belonged to ‘poor socio-economic’ group, reported from the rural area.

In the present study, it is noted that 50% were in stage III-IV of cancer and hardly 2% was in stage I cancer, whereas the Annual Report, 1998 of Hospital Cancer Registry, RCC, Trivandrum (2001) showed 36% of cancers in stage I & II, 50% in stage III and 14% in stage IV, out of the 178 cases in whom staging was done. As earlier stage of detection and treatment are equated to better prognosis, one of the strategies adopted for cancer control is down staging of cases at diagnosis and treatment. In India it is well known that a great majority of patients present for treatment in a very advanced stage of disease. The Tata Memorial Hospital data has indicated that 39% of breast cases among illiterates had stage III and IV compared to 19% in College Educated Women (Rao & Dinshaw, 1999). The present patient attendance in hospitals indicates that only less than 10% attend for treatment in stage I disease. According to Gangadharan (2001), “the necessity for early detection of breast cancer, when cure rates can be above 90%, needs to be propagated in view of the fact that at present there are no known powerful modifiable life factors. The need is thus for early detection and to follow strict treatment protocol developed and tested in Indian setting”. It appears very much relevant since stage 1 breast cancer patients were very few in the present study.

In the present study, all subjects had undergone modified radical mastectomy and a majority (61%) had chemotherapy prior to undergoing
radiation therapy to chest wall and drainage areas and the duration of treatment varied from 0.25 years to 12 years or more with a mean duration of 1.33 years whereas the mean time since breast cancer diagnosis was 3 years in Ferrell et al (1996) and all women had surgical treatment of cancer, with 76% having mastectomy and 24% lumpectomy of which 81% had chemotherapy and the same percentage also had radiation therapy. According to the study conducted by Ferrans (1994) on quality of life through the eyes of survivors in breast cancer, consisting of 61 women who had been diagnosed with breast cancer, the mean age was 52.28 years; the mean length of time since diagnosis 10.28 years; ninety seven percent had undergone surgical treatment for breast cancer, 15% had radical mastectomy, 59% had modified mastectomy, 7% had single mastectomy, and 7% had local excision only. In addition 46% had chemotherapy and 30% had radiotherapy. These findings are more or less consistent with the present study.

The mean QOL scores also showed no appreciable difference in different age groups and different religious groups. However, the place of residence and education showed certain relationships with that of the mean baseline QOL score, though not statistically significant. Dow et al, (1996) compared the subjects with length of time since breast cancer diagnosis with regard to the subscales and total QOL score and found that on all four subscales of Physical, Psychological, Social and Spiritual well being as well as the total QOL scores, length of time was significantly related with better outcomes in each area with longer time since diagnosis (P<0.05). Numerically these findings are in conformity with the present study but were not significant statistically except in the case of stage of cancer.

Sloman et al (1994) in his study to test the efficacy of relaxation technique involving deep breathing, muscle relaxation and imagery reported that age of the subject ranged from 37 to 80 with a mean of 64 and all subjects were in the intermediate or advanced stages of cancer. Hence he found significant reduction in subjective pain ratings by subjects receiving relaxation training and that age, gender and diagnosis made no significant moderator effect. Again in another study, Sloman, (1995) tested the age,
gender and type of cancer diagnosis as possible moderator variables on the pretest-post test difference scores and no significant moderator effect was found at the 0.05 levels. These results are quite agreeable with the present findings.

**ANXIETY & DEPRESSION IN BREAST CANCER**

It is estimated that approximately 85% of the women with breast cancer experience anxiety and that feelings of fear and stress may be universal (Achte & Vauhkonen, 1971; Scott & Eisendrath, 1986; Samarel et al., 1997). The most commonly reported psychological side effects of cancer treatment is depression (Maunsell, et al., 1992; Munkres, et al., 1992; Northouse, 1990).

In the present study, the baseline mean anxiety and depression scores showed no significant difference between different age groups, between different place of residence, education, religion etc. The mean anxiety and depression score also showed no difference in chemotherapy ‘availed group’ and ‘not availed group’ during pre assessment. Also the mean HAD scores were same irrespective of duration of treatment and stage of cancer.

Women who experience depression and who report depression burden may have decreased abilities to benefit from self-help promoting interventions, and some evidence suggests that depression may influence not only women’s self-care activities but also their survival time (Spiegel, 1997). According to Badger, et al (2001), both depression and fatigue are highly problematic side effects for women diagnosed with breast cancer.

Anxiety is a frequent accompaniment of depression and is seen up to 15% of cases (Levine, et al., 1978); depression is the most common problem seen in as many as 50 percent of cancer cases and is reactive for being stress response to illness (Brown & Paras, 1982; Roose, et al., 1983); a diagnosis of cancer is often associated with a host of negative emotional responses including depressed mood (Godding, 1995). According to Massie (1990), numerous studies have been done to determine the actual incidence of depression in cancer patients and it is generally assumed that at least
25% of all cancer patients will meet criteria for adjustment disorders with depressed mood or major depression. Thus depression ranks among the most frequent psychological side effects for women with breast cancer and poses significant threats to functioning, health/well being, and long term survival (Badger, et al., 1999; Lewis, et al., 1996; Pasacreta, 1997; Waxler Morrison, et al., 1991). Prior to intervention, in the present study, the mean Anxiety score ranged from 10.1 to 12.5 and the mean Depression score ranged from 8.2 to 10.9 in the 3 groups. These findings are well supported by the above studies.

Fifty seven percent of patients with cancer report depression symptoms such as depressed mood, difficulty concentrating, and difficulty sleeping as problematic side effects of cancer and its treatment (Barsevick, et al., 1995; Depression Guideline Panel, 1993; Pasacreta and Massie, 1990; Sachs et al. 1995). Besides, Smith et al (2001), concluded that Radiation in cancer treatment can induce fear and anxiety in patients. These findings are in conformity with the present study. But the study does not support Hughson, et al. (1987) who examined the psychological -effects of radiotherapy following mastectomy in order to elicit if postoperative radiotherapy induced more psychological and social morbidity and found that receiving radiation therapy did not lead to increased levels of anxiety or depression.

In the present study, after the first intervention, during post assessment I, the mean anxiety score showed slight increase in C group whereas there was a reduction in the mean scores of R group (8.4) and of FM group (9.8). After the 7th intervention, during post assessment II, the reduction seemed to be highly statistically significant. This conforms with Dunn et al (1995) who found that patients who had received a Foot Massage reported improved mood and reduced anxiety. Patients using complementary therapies were shown to be more anxious initially as rated by the Hospital Anxiety and Depression scale, than those receiving conventional treatment only. Patients who attribute the cause of their illness to something within themselves may carry an undue burden of responsibility for their illness and thus become anxious (Downer, et al., 1994). These results are further supported by the present study too.
At the time of post assessment II, R & FM groups showed more or less the same level of mean anxiety score (7.63 in the R group and 7.33 in FM group) whereas the mean anxiety score of Control group continued to be very high (12.17). Even in the case of depression, there was significant reduction in R and FM groups though initially during pre assessment no appreciable difference was observed. During post assessment II the mean depression score in R group was 7.7 and in FM group 6.6 compared to 10.5 in C group. In 95% of subjects studied the depression score ranged from 6.90 to 8.63 in R group and 5.27 to 7.92 in FM group. Hence in the present study as a response to the interventions the anxiety and depression were significantly reduced by post assessment II.

However, a longitudinal study done by Chaturvedi, et al (1996), Anxiety and Depression at varying levels in a study of 100 newly diagnosed consecutive adult patients of all cancer sites beginning radiation therapy, focusing on changes in Anxiety & Depression, starting at the first contact before being told about the treatment plan, just before starting RT and at 3-4 months follow up. Anxiety and depression were noted in all levels at varying levels. But a significant increase of anxiety (P<0.05) was noted at the second assessment, around the time they were being asked to consider radiotherapy treatment, and also at the time reported for 3-4 months follow up. The second assessment in his study is just the point of time(pre assessment) in the present study, i.e., when the subject was explained about the RT prior to the intervention and therefore the finding is in supportive of the present study too. Chaturvedi suggested that the anxiety and depression noted prior to treatment and later during follow up could be helped by psychological interventions and counselling. Following either of the two interventions, in the present study, the anxiety and depression levels were significantly reduced from a fairly high level to a moderate range more in line with those reported by Spielberger et al (1983).

While considering the individual factors of HADS, all the 3 groups were identical during pre assessment. At the same time during post assessment I, F3 ‘frightened’ showed maximum reduction in R group. Regarding FM group
the maximum reduction was in F9 ‘feeling like butterflies’; F10 ‘appearance’ and F11 ‘feel restless’. The majority of these differences were statistically insignificant. However, during post assessment II almost all factors recorded highly significant reduction in HAD factors. The maximum result obtained in F3 ‘frightened’ and F6 ‘feel cheerful’ of FM group and F1 ‘feel tensed/wound up’ and F10 ‘appearance’ of FM group. So it appears from the present study that these minor details can be deleted to ascertain the HAD scores.

**QUALITY OF LIFE IN BREAST CANCER**

A woman’s breast can be a powerful symbol of womanliness, sex attractiveness, and nurturance (Mock, 1993). The loss of a breast can result in a degradation of body image and self-concept. The magnitude of the change is thought to depend on the degree of physical change and the meaning of the breast to the woman (Mock, 1993). A growing consensus shows that intermediate and late physical effects, changes in psychological make up, concerns over changes in the family and work settings, and spiritual aspects of having survived a life-threatening disease are greater influences on perceptions of quality of life in long-term.

Moreover, according to Dow, et al., (1996), women with a history of breast cancer have on-going psychosocial needs and concerns that are critical to address in long term follow-up and according to Ferrell, Dow, & Grant (1995), women cancer survivors express physiologic changes such as fatigue, aches, sleep problems, social problems, social concerns (e.g., family distress, sexuality, family burden issues), psychological distress with fear of recurrence, and spiritual needs as a result of uncertainty over the future and positive outcomes such as a sense of hopefulness, having a life purpose, and positive changes following treatment.

The findings of the present study revealed that the demographic characteristics such as age, place of residence, level of education and religion did not show any statistical significance in the mean QOL scores. Also no significant difference in the pre assessment means of QOL-BC scores was observed according to disease profile except in the case of stage of cancer
and that too only in Physical domain whereas according to Ferrell et al. (1998) many variables, including age, pain, type of treatment and time since initial diagnosis, have been found to be important determinants of overall QOL requiring special consideration in breast cancer populations. Also, Ganz et al., (1992) found a real positive relationship between age and QOL in women with breast cancer.

In the Physical well being of the subjects the difference between the three pre assessment mean scores of C, R and FM groups showed no statistically significant difference and so all the three groups were having more or less similar Physical well-being score prior to intervention. From the Pre assessment mean score of 40.03, C group showed further deterioration in the Physical well being score reducing to 37.1 in Post Assessment I and 30.07 in Post Assessment II. At the same time, there was considerable improvement in R group while comparing with the pre assessment (from 39 to 49.7 and to 57 during Post Assessments I & II respectively) and in FM group (from 36.4 to 44.9 and 57.4 during post assessment I & II respectively), invariably these differences being highly statistically significant (P< 0.01), in both the groups.

From the comparison of mean increase noted in the Physical well being domain it became evident that both the interventions, Simple Rhythmic breathing Relaxation (SRBR) and Foot Massage (FM) were very effective in improving the Physical well being scores of the subjects, the maximum effect being recorded in Foot Massage group during post assessment II, numerically; however, the difference in the increase noted between R & FM groups was found to be statistically not significant (P>0.05). Hence it is concluded that both the interventions were effective in increasing the Physical well-being scores, FM showing more effectiveness if the duration of intervention was increased.

In the Psychological well being, there was deterioration of mean scores (from 85.70 in pre asst to 77.50 and 66.40 in post asst I & II respectively) in C group; increase of mean scores (from 84.20 in pre asst to 103.8 and 115.70 in post I & II respectively) in R group and again, increase of mean score (from 6.37 in pre asst to 84.57 & 105.13 in post asst I & II respectively) in FM group.
From the significant differences and the increased comparison scores it was concluded that both SRBR and FM were effective, FM being more effective in enhancing the psychological well-being scores irrespective of the duration of the intervention.

While considering the mean Social concern scores, C group showed marked decline in the scores (from 33.70 in pre asst to 28.20 in post I and 25.33 in post asst II) whereas there was increase in R group (from 36.83 in pre asst to 39.90 and 47.17 in post asst I & II respectively) and in FM group (from 25.40 in pre asst to 30.90 and 37.10 in post asst I & II respectively). Though these differences were significant, there was only marginal increase noted between R & FM groups. Hence it was observed that both the interventions had more or less same level of improvement, more of it noted in post asst II whereas C group showed marked decline in the scores.

In the case of Spiritual well-being there was tremendous improvement on account of the interventions. The C group showed decline (from pre asst scores of 48.10 to 47.80 and 45.70 in post asst I & II respectively) whereas there was improvement in R group (from 50.13 pre asst to 52.43 and 56.47 in post asst I & II respectively) and also in FM group (from 51.97 to 54.87 and 57.40 in post asst I & II). During post asst II, the improvement noted in R & FM groups were found to be significant at a very high level (P<0.001). Hence both SRBR and FM were found to be effective in enhancing the spiritual well-being scores.

The findings of the present study on QOL-BC factor analysis has been compared with the study conducted by Ferrell, et al (1996) on Quality of Life in Breast Cancer. Accordingly, in Ferrell, et al, in the Physical well-being, the areas of worst outcome were in ‘menstrual changes and fertility (4.12)’, ‘fatigue (6.48)’, and ‘pain (6.95)’ etc whereas in the present study during post assessment II, the least changes were noted in the case of ‘fatigue (mean=6.4 in R and 6.27 in FM)’; the predominant needs illustrated in the areas of Psychological well-being were ‘fear of spread of cancer (3.04)’, ‘distress from surgery (3.05)’, ‘recurrent cancer (3.50)’, ‘fear of second cancer (3.95)’, ‘impact on self-concept (4.04)’ and ‘fear of future tests (5.00)’ etc whereas in
the present study, ‘fear of a second cancer (mean=3.83 in R and 2.5 in FM groups)’, and ‘fear of recurrence (mean=3.5 in R and 2.43 in FM groups)’; in the Social well-being greatest disruption was identified in the area of ‘family distress, with an extreme score of 2.00’; the spiritual well being, showed a greatest disruption in the area of ‘uncertainty (4.24)’ whereas in the present study, ‘concern for female relatives (2.93 in R and .83 in FM groups)’; and ‘uncertainty about future (mean= 4.23 in R and 3.53 in FM groups)’ in Spiritual well being domain.

Rustoen, et al., (1999) conducted a study to examine which domains of quality of life are most strongly affected in patients with newly diagnosed cancer, and if quality of life was related to gender, age, educational level, cohabitation, time since diagnosis, treatment or type of cancer. To measure QOL he used Ferrens and Powers’ Quality of Life Index (QLI) and the Cancer Rehabilitation Evaluation system, short form (CARES-SF) tools in 131 newly diagnosed Norwegian adult cancer patients who had different cancer diagnoses, but the majority had breast and gynaecological cancers. The mean time since diagnosis was 5 months The highest QOL mean scores of the patients in QLI included relationship with spouse (10.0), friends (9.6), emotional support from others (9.6) children (9.1), home (9.0 and family’s health (8.8) and the highest QOL mean scores in CARES-SF included difficulty bathing, brushing teeth or grooming (0.07), difficulty asking for time off from work for medical treatments (0.13), difficulty talking about cancer to the people who work with (0.17) and so on. These findings are also consistent with the above study findings.

The study conducted by Ferrell, et al., (1998) to evaluate the QOL needs of breast cancer survivors in order to provide improved supportive-care services included 298 breast cancer survivors who completed a mailed survey that included major outcome variables of QOL and pain. Subjects were stratified by (1) younger than 40 years,(2) 40-60 years, and(3) older than 60 years. QOL subscales (Physical, Psychological, Social and Spiritual well-being) and overall QOL score were assessed by using the 46-item QOL-Breast Cancer Version (QOL-BC) and pain was assessed by the 14- item
Brief Pain Inventory (BPI). The QOL-BC scores transposed as 0=worst outcome and 10= best outcome showed that the worst outcomes were in the area of psychological well-being (X=6.30) whereas in the present study the domain-wise comparison of the two interventional groups showed maximum increase in Physical domain with the least change in Spiritual domain.

Sarna and McCorkle (1996) suggested that increasingly, intensive cancer therapies used to treat breast cancer can produce severe and sometimes life threatening side effects, an inability to tend to self care needs, and often total dependence on caregivers and according to Hughson, et al. (1987) those who received radiation therapy felt more lethargic had more social dysfunction and had more symptoms 3 months after the surgery.

The present study results of the Physical well being reflected the lingering effects of fatigue on breast cancer survivors and the need to implement programs addressing to these areas. In the area of Psychological well being they need information about the facts associated with recurrence and available treatments for recurrent disease just as suggested by Ferrell et al, (1995). On the Social concern subscale, family support interventions need to command more attention, particularly as the traditional family constellation changes. The worst outcome noticed in the Spiritual domain reflects the need to continue to assess the positive aspects of the illness in the spiritual realm whereas spiritual support was found to be important in other studies of people diagnosed with cancer (Padilla et al., 1990; Raleigh, 1992). Survivors of breast cancer had spiritual experiences that strengthened them during their most vulnerable times of diagnosis and early treatment (Wyatt, et al., 1993). But in another study Wyatt and Friedman (1996) sought to identify concerns and issues related to QOL in long-term female cancer survivors who were recruited through a Michigan tumor registry. QOL data were collected from mailed questionnaires from 188 long-term female cancer survivors with a mean age of 61 years and the results showed found that the lowest levels of QOL were in spiritual/ philosophic views, diet and exercise habits, and social/ emotional support; the highest area of QOL was in physical well being.
Dow et al (1996) conducted a descriptive study that evaluated the quality of life of 294 breast cancer survivors in order to review the continuum of positive and negative QOL outcomes in this population. The main research variables were the subscales (Physical, Psychological, Social and Spiritual well being) and the individual items of the Quality of Life-Cancer survivors’ tool and the Functional Assessment of Cancer Therapy (FACT-G). Results indicated that: a) fatigue, aches and pains, and sleep problems were persistent after treatment ended; b) psychological distress from cancer diagnosis and treatment, and fear of recurrent, metastatic, and recurrent disease were problematic over time; c) family distress, sexuality, and family burden issues were of greatest social concern; and d) uncertainty over the future plagued breast cancer survivors long-term. These findings are also consistent with the findings of the present study.

Dow & Latterty (2000) studied the changes in quality of life, psychosocial adjustment, and survivorship issues over time of 23 women younger than 45 years with newly diagnosed Stage I or II breast cancer who were starting RT following breast-conserving surgery with a mean age of 37.8 years. Data were collected at start of RT, midpoint of RT, end of RT, and six months after RT using Quality of Life Index, Psychosocial Adjustment to Illness Scale, and the newly developed Adaptation to Survivorship Experience. The findings showed that the QOL declined from the start of RT to midpoint, with gradual improvement reported six months later. Social and sexual adjustment declined from start of RT to six months later. Negative perceptions of the survivorship experience and worry about cancer increased from the start of RT to six months later. Follow –up paired- samples t –tests showed a statistically significant difference between the start of RT and at six months with regard to improved level of overall psychosocial (p=0.01) and social adjustment (p=0.002). These findings are consistent with the present study findings and point out the needs for intervening with specific behavioural therapies which might help in reduction of negative perceptions of the survivorships.
EFFECT OF SRBR & FM ON HAD & QOL –BC SCORES

While considering the effectiveness of Simple Rhythmic Breathing Relaxation (SRBR) on Anxiety/Depression in R group, the mean pre anxiety score of 12.50 was reduced to 9.80 initially and then to 7.63 during post assessment II. Similarly the mean Depression score reduced to 7.77 during post assessment II from the pre assessment score of 10.90. With the highly statistically significant reduction (p<0.001) it is thus established that the Relaxation technique provide significant reduction in Anxiety and Depression and its effectiveness is found to be increasing according to duration of intervention.

Similarly, while considering the effectiveness of Foot Massage in reducing Anxiety/Depression, FM group had a pre-assessment mean Anxiety level of 10.1, which was reduced to 8.40 and 7.33 during post assessment I & II respectively. In the case of Depression also, the pre- assessment mean score of 8.2 was reduced to 7.40 and 6.60 during post assessment I ((P>0.05) &II (P<0.05) respectively. Thus Foot Massage is proved to be an effective intervention to reduce Anxiety and Depression and its effectiveness is found to be increasing if the period of intervention was increased.

While assessing the effectiveness of SRBR in improving the QOL in R group the mean pre assessment physical well being score of 39 was increased to 49.7 and to 57 during post Assessment I & II (P<0.001) respectively. A similar increase recorded invariably in all the other three domains too (and the difference happened to be significant statistically at a very high level P<0.001). The level of effectiveness showed an increasing trend if the duration of treatment was increased. And so it became evident that SRBR was not only effective in bringing down the Anxiety and Depression but also in increasing the QOL in all the four domains.

Similarly while considering the effectiveness of Foot Massage, in the mean QOL scores, the improvement was highly statistically significant (P<0.001) in all the four domains except in the Spiritual well being domain during post assessment I. At the same time, in the other domains the
differences were highly significant. During post assessment II, the Physical and Psychological well being scores showed a two-fold increase (Physical well being score increased to 57.37 from the pre assessment value of 36.40 and Psychological score to 105.13 from 60.37). Even the Social and Spiritual domain scores also showed highly significant increase during post assessment II. Hence it is observed that Foot Massage was effective in enhancing the QOL scores in all the four domains though with slight fluctuations.

The inter domain effectiveness of the two interventions was compared taking the total quality of life in each domain as 1 or 100%. Then in all the 4 domains no significant difference noted in the pre assessment QOL-BC level and it varied from 0.46 to 0.51 in physical well being, 0.27 to 0.39 in Psychological domain, 0.28 to 0.40 in Social domain and 0.61 to 0.74 in the Spiritual domain. During post assessment 1 there was significant increase in all the four domains of the intervention groups. During post assessment II, R and FM groups showed maximum improvement in Physical domain while the minimum being recorded in the Spiritual domain.

The correlation analysis of the variables established positive correlation between Anxiety and Depression. Similarly for every unit increase in the Physical quality of life, there was a proportionate increase in the other QOL domains. At the same time there was negative correlation between HAD scores and QOL scores.

Sloman, et al (1994) studied the efficacy of progressive muscle relaxation and mental imagery as a nursing intervention for the management of cancer pain in patients with intermediate or advanced stages of cancer admitted to an oncology ward. Sixty-seven patients (48 males and 19 females) were randomly assigned to one of three groups: (1) audio tape instruction on relaxation training (PMR+MI); (2) live instruction on relaxation directly by the registered nurses; and (3) control group who received no specific training in the use of relaxation. Relaxation training was conducted twice weekly over a period of 3 weeks. Each subject was pre - tested with the Short- Form McGill Pain Questionnaire (SF-MPQ) and Visual Analogue Scale
(VAS) for pain followed by a two week regimen of either taped relaxation sessions using earphones (audio tape group), live nurse-directed relaxation sessions (live group), or no relaxation sessions (control group). Treatment subjects received two relaxation training sessions in the first week followed by another two in the second week and all of them were encouraged to practice the technique twice daily, morning and evening. Subjects were post-tested at the end of the third week. Treatment subjects were also asked to complete a short questionnaire concerning the extent to which they utilized the relaxation technique and how well they were able to achieve a relaxed state. Analgesic medication was monitored throughout the study. Findings showed that there was a significant treatment effect for pain sensation (F=3.936, P<0.05) and present pain intensity (F=14.642, P<0.001) in subjects receiving relaxation training. There was also significant reduction in non-opiate p.r.n analgesia (F=8.160, P< 0.005) that suggested a reduced incidence of break through pain. These findings are consistent with the findings of the present study in terms of reduction in HAD Scores and increase in QOL-BC scores.

The study done by Sloman et al (1994) on the use of relaxation for the promotion and comfort and pain relief in persons with advanced cancer strongly suggest that relaxation can be effectively taught to cancer patients by either audio tapes or by direct live teaching by nurses whereas it is suggested by the present study that relaxation can easily be achieved by breast cancer patients if they are given little training on the relaxation technique and provided with recorded cassette on the same.

Aivazian, et al (1988) studied the efficacy of relaxation techniques in hypertensive patients by examining 117 outpatients (20-45 year old men) with mild essential hypertension before treatment, after 6 weeks and at 12 months follow up. The patients were randomized for (a) autogenic training (n=23), biofeedback (n=24), or breathing relaxation training (n=23) and (b) a control group (n=24) with no intervention, and another group (n= 23) who were treated with a 'psychological placebo'. Analysis of the clinical, psychological and physiological data from all patients who were offered relaxation therapy demonstrated a significant reduction in the treatment group in systolic and
diastolic blood pressure, peripheral vascular resistance and hypertensive response to emotional stress and an improvement in psychological adaptation, quality of life, and capacity for work. Comparative analysis of the efficacy of different relaxation methods revealed that bio feedback and breathing relaxation training resulted in the greatest reduction in blood pressure.

Sarah (1993) studied the effectiveness of Jacobson’s Progressive Muscle Relaxation on 30 subjects (20-25 yrs) with premenstrual syndrome. Relaxation training was given to these subjects continuously for a month, starting after 4 days of menstruation, till the next menstrual date and the results indicated that there was significant decrease in the scores of premenstrual syndrome after relaxation. Similarly, George (1995) found that relaxation reduced premenstrual distress and there were considerable reduction in somatic and psychological symptoms. Lyles, et al., (1982) conducted a controlled clinical study on the efficacy of relaxation training in helping to control anxiety, nausea and vomiting in 50 patients with cancer who were receiving chemotherapy. Subjects were trained in both muscle relaxation and imagery techniques. The results showed a significant reduction in patient- reported, nurse- reported and physiological indices of distress in patients who received relaxation training.

Joy and Sreedhar (1998) studied the effectiveness of Guided Somato-Psychic Relaxation (GSPR) developed by Sreedhar (1996) in the management of essential hypertension and its related psychological factors like anxiety and depression on 7 female mild essential hypertensives who were under medication with the same drug and dosage. Of this, 4 constituted the study group. Small-N design with pre-assessment, mid- assessment and post-assessment was used for the study. The assessments consisted of the measurements of blood pressure (both systolic & diastolic), anxiety and depression. Each subject was given a total of 10 relaxation sessions, and the mid-assessment was done after the 5th session and a follow up at two weeks while the control group was used only for the various assessments. The findings showed considerable reduction in the levels of blood pressure,
anxiety and depression in the study group while the control group had very little variations in the levels of blood pressure, anxiety and depression. Hence the study concluded that GSPR is effective for patients with essential hypertension and its related psychological factors like anxiety and depression.

From above studies it is seen that relaxation techniques are being used in a variety of situations by variety of modifications; the present study being another model of the same and the findings of such have much similarities in terms of reduced anxiety & depression, lowered blood pressure and increased sense of well being etc. Hence such findings are supportive of the present study too where a reduction in anxiety & depression and increase in QOL scores were observed as the result of two interventional modules.

It could be argued that by massaging the foot the instructor may inadvertently apply pressure to reflexology points that are thought to produce an analgesic effect as stated by (Davis 1988). The present study used a simple massage technique without pressure on the points, indicated on a reflexology foot massage. Although the same basic strokes were performed, the speed, pressure and repetition of each movement was tailored to fit the individual and it is consistent with the procedure suggested by Hulme et al, (1999) and Hayes and Cox (1999).

Women affected by breast cancer comprise a very unique group with particular problems and this study was able to address their psychosocial symptoms in a feasible manner. The modules generated were proved to be effective and found to be acceptable for the population as none of the potential subjects were approached, declined to participate which is in supportive of Sloman(1995). The delivery of the interventions was possible with minimum alterations in the infrastructure. The cent percent consent rate for this study, supported by the literature (Hulme et al, 1999;Tappan,1988; Stevenson 1992,1994) suggest that the design was acceptable to potential participants and no coercion was applied by the investigator.

Physiological results have in general shown no significant difference in heart rate, arterial blood pressure or respiratory rate (Dunn, 1992).
Psychological effects generally include positive results in terms of subjective response (Madison, 1973), the perceived state of relaxation (Longworth, 1982), pleasurable feelings reported (Bauer & Dracup, 1987) and an improvement in the perceived level of anxiety and mood (Dunn, 1992). The present study is supportive of these results, where reduction in the anxiety and depression and increase in the mean QOL-BC score are observed.

A number of studies have been performed using massage of different body areas and for varying length of time. Many nurses express the concern that they do not have enough time to administer complementary therapies to their patients. The duration of intervention chosen for the present study was 20 minutes so as to allow time for possible physical and psychological relaxation. This conforms to the studies that of Hewitt (1992) and Stevenson (1994) who state that Foot Massage lasting between 17 and 20 minutes is as beneficial. The HADS/QOL-BC findings of the post assessment I of the present study is also consistent with Hayes and Carol (1999) who found that a brief Foot Massage, lasting only five minutes, can be an effective intervention for reducing stress and anxiety and promoting relaxation and who suggested that Foot Massage is a reasonable intervention, which can be administered to patients even if in intensive care. A longer massage, for a 30 minute may have been beneficial to the participants and might have produced a significant effect according to Kaada and Torstein (1989). Since endorphin is usually released after a 30-minute massage, in a practical situation, this time scale may not be feasible. Harrison (1986) states that massage is invaluable for helping to relieve tension, alleviate fatigue and instill deep relaxation. The present study findings are also quite agreeable to Harrison since both the interventions were effective in inducing relaxation and relieving tension and fatigue.

Wilkinson (1999) studied the effects of massage and aromatherapy on 103 cancer patients by randomly allocating the subjects to receive massage using a carrier oil (massage), or massage using carrier oil plus the Roman chamomile essential oil (aromatherapy massage) by using the Rotterdam Symptom Checklist (RSCL), the State-Trait Anxiety Inventory (STAI) and a
semi-structured questionnaire, administered 2 weeks post massage, to explore patient’s perceptions of massage. There was a statistically significant reduction in anxiety after each massage on the STAI (P<0.001), and improved scores on the RSCL: psychological (P<0.001), quality of life (P<0.01), severe physical (P<0.05), and severe psychological (P<0.05) subscales for the combined aromatherapy and massage group. These findings are supportive to the findings of the present study.

Sims (1986) conducted a pilot study to evaluate the effects of massage with cancer patients using a cross-over design with six women undergoing radiotherapy for breast cancer and found that the women reported a 25% improvement in symptom distress following the massage, compared with an 8% improvement in the control intervention. There was also an overall mood improvement of 18% following massage compared with 14% for the control intervention. Although patients’ comments following the massage were of positive nature, none of the differences reached statistical significance. He contended that the purposeful use of touch has significance for all patients and that it has particular significance for patients with far advanced disease.

Lorensen (1983) found that touch during labour, including a gentle back rub, was perceived as helpful by twelve primigravidae in relieving the discomfort of childbirth. Joachim (1983) carried out a small pilot study to determine the effects of deep abdominal breathing and massage on the well-being of fifteen patients with inflammatory bowel disease and found that massage rather than deep abdominal breathing made them feel more relaxed. The poor research design and lack of control group severely limit the significance of these findings.

When asked to comment on the personal experiences on Simple Rhythmic breathing Relaxation / Foot Massage, most subjects commented as ‘very relaxing’, ‘feeling no weight of the body’, ‘peaceful’, ‘calming’, wished if the duration was longer’. Most of these comments concur with the study done by Stevensen (1994) where patients who were able to communicate—especially those who were to be discharged from the intensive care unit to the ward environment, indicated that they looked forward to their sessions of Foot
Massage and said that they felt the Foot Massage helped them relax and was more pleasant than the interventions normally provided by nursing and medical staff and also with that of Passant (1990) who stated “that Massage brought many benefits to our patients. Touching in this beautiful and asexual way opened the door to a closer relationship with us, allowing patients to speak of their dreams and hopes, of their fears and pleasures. To relieve stress and pain on all levels was something I had not thought possible—but it is.” The findings in the present study also suggest that even if the physiological benefit is transient, the psychological benefit gained is substantial just as stated by (Hayes and Carol, 1999).

During massage some people want to talk while others prefer a relaxed silence. Unless the person prefers otherwise, music is usually played. Indeed, Garnett’s (1994) study on four Complementary therapies in Palliative care found that a high number of people preferred to listen to a sound whilst experiencing the therapy. This is well supported by the present study as the subjects in both the intervention groups commented positively on the background music played and they preferred a relaxed silence.

In terms of any quasi-experimental research design, confounding variables must be considered as a possibility influencing the results (Hayes and Cox, 1999). In order to limit potential influencing factors, the treatment protocol provided for (1) only one visitor was allowed to be present during the intervention; (2) no conversation was permitted during the intervention; and (3) only one person—the investigator, administered the intervention to all the patients. The feet were readily accessible in this study and no repositioning was required, thus avoiding what might otherwise have been a confounding variable. Foot Massage was chosen as it is considered to be ‘grounding’ by its nature and easily available, accessible and comfortable for patients who are physically weak and psychologically depressed as was opinioned by Stevenson (1994).

A good number of subjects felt that a run of seven consecutive interventions was helpful. This finding is supported by Corner et al (1995) who found that the duration of the effects of massage on anxiety was 2-4 days, the
effects were cumulative and that the peak effect was felt after four sessions. In the present study this again confirms with the significant reductions noted in anxiety and depression during post assessment II (on day 7). Stevenson (1994), who used Foot Massage on patients following cardiac surgery, did not report patient distaste of Foot Massage as a problem to recruitment. In the present study, although the subjects were unaware of the intervention at recruitment time, none of them expressed any distaste for the particular intervention—including Foot Massage applied on them. Since it is practice to perform massage on both limbs to achieve balance (Tappan 1988, Stevenson 1992, 1994), in the present study also the same procedure was followed.

Stevenson (1994) noted psychological benefits of aromatherapy Foot Massage in intensive care. However, in his study, there was no such effort to see whether the beneficial effect was due to the Foot Massage or due to the complemented effect of the essential oil applied. To avoid this uncertainty, in the present study, only a base oil (arnica) was used to prevent friction and possible damage to the patient’s skin during the Foot Massage. Arnica oil was chosen as a lubricant because it is well absorbed into the skin, which is non-sticky, odorless and harmless to the skin. It strengthens the elderly skin, makes it more elastic, thus preventing bruising and causing damage to the skin. This is further supported by Davis (1988) who used grape seed as base oil, which can be used by those who suffer from nut allergies.

This study provides evidence to support the efficacy of a relaxation procedure incorporating SRBR and FM for the reduction of Anxiety and Depression and enhancement of Quality of life in breast cancer patients. But the results were transient as there were variations in post assessments I & II. Stevenson (1994) reported similar findings of transient results. This lack of consistency could be attributed to the brief period of the interventions. The current practice of treatment of anxiety and depression through pharmaceutical and counseling methods are of use. However in a busy cancer hospital there will be many limitations in personnel, finance and other requirements for providing this service. Further research in this area is needed to replicate this study and to test the application of relaxation
techniques with family members of persons suffering with a diagnosis of breast cancer. The use of relaxation techniques to help family members and significant others cope with such stress should be researched as suggested by Sloman (1995). The techniques can be taught by nurses and readily learned by patients.

Although the study addressed multiple concerns across four QOL domains, many other QOL concerns such as lymph edema (Ferrell.1998), in addition, coping mechanisms for the family and follow up regimen could also be included in future studies. However the study findings will be instrumental to the investigator in designing more comprehensive care within existing settings.

CONCLUSION

It has been established that the control group showed a statistically significant increase and that the R and FM groups made significant reduction in HAD score and no further statistical test was found necessary to compare the changes in the control group with that of R and FM groups. Hence it is concluded that there was significant reduction in HAD scores between patients with breast cancer receiving no intervention (Control group) with those receiving Simple Rhythmic Breathing Relaxation(R Group) and Foot Massage (FM group). In other words the two interventions were found to be effective in reducing HAD scores compared to the non-intervention group.

Also in the case of Control group there was deterioration in all 4 domains of QOL whereas there was an improvement invariably in R and FM groups. Hence it is established and concluded that there was significant increase in QOL-BC scores of subjects receiving Simple Rhythmic Breathing Relaxation(R Group) and Foot Massage (FM group) than subjects receiving no intervention (Control group).

In fact it is established that both the interventions were effective in reducing HAD scores but the Relaxation Technique was found to be superior in this regard. Also, the findings on the QOL score revealed that the increase
in both the groups was significant and therefore it is established that the effectiveness in increasing mean QOL-BC scores by Simple Rhythmic Breathing Relaxation Technique (R Group) was different than that of the effectiveness of Foot Massage Technique (FM Group). In this case it is proved that both the interventions were effective in increasing the QOL-BC score but the FM group appeared to have slightly better effect than that of the R group in all the four domains except in 'spiritual domain', wherein R group gave better results.

From the analysis it is found that Simple Rhythmic Breathing Relaxation Technique (R Group)/ Foot Massage Technique (FM Group) has got effect by itself in reducing mean Anxiety/Depression scores and thereby in increasing QOL-BC mean score. The effectiveness noted even in the case of HAD/QOL-BC factors.

The FM group showed 21% improvement in psychological domain and 24% improvement in social domain compared 15% and 12% respectively in R group. These differences happened to be statistically significant (P<0.05). Thus the QOL showed better improvement in FM group except in spiritual domain. Out of the four domains, physical domain showed maximum improvement in both the groups whereas the least effectiveness is seen in spiritual well being domain. Therefore the effect of Simple Rhythmic Breathing Relaxation Technique (R Group) and Foot Massage Technique (FM Group) was different in all the 4 domains—Physical, Psychological, Social and Spiritual". It is found that the improvement in QOL score was more in Physical domain irrespective of the type of intervention and the least in the Spiritual domain.

The correlation analysis of the HAD/QOL domain variables revealed that there was correlation between (a) Anxiety score and Depression score, (b) HAD score and Physical domain and (c) Physical domain and the other 3 domains--Psychological, Social and Spiritual irrespective of the mode of intervention". In this case it is established statistically that there was positive correlation between Anxiety and Depression but negative correlation between
the HAD score and QOL-BC score. Also the Physical domain score showed strong positive correlation with the other domain scores.

The study showed that Relaxation and Foot Massage might be helpful in relieving anxiety and depression in hospitalised patients and in improving their quality of life in the Physical, Psychological, Social and Spiritual dimensions. The findings also suggest that anxiety & depression and quality of life are negatively related. Hence for increased well being status a decreased anxiety & depression level is necessary which can result through complementary therapies such as Simple Rhythmic Breathing Relaxation and Foot Massage.
CHAPTER 6

Summary
Conclusions
Implications of the Results
Limitations of the Study
Recommendations