CHAPTER 6

SUMMARY, CONCLUSIONS, IMPLICATIONS
LIMITATIONS & RECOMMENDATIONS

This chapter presents the study in retrospect and summary of the findings. Further it presents the conclusions drawn, implications for the Nursing Practice, Nursing Education, and Nursing Research. It also presents the Limitations of the study and the Recommendations for future research in this field.

SUMMARY

Among females, Breast Cancer claims the major share of all types of Cancers. Breast Cancer patients are most vulnerable to anxiety and depression. The increase in anxiety ends up in depression and a composite effect of anxiety and depression crops up considerable reduction in the quality of life.

Generally complementary therapy is a neglected area of research, but the present study has shown that it is feasible to evaluate the impact of two selected complementary therapies such as Simple Rhythmic Breathing Relaxation (SRBR) and Foot Massage (FM) on the Quality of Life (QOL) of breast cancer patients undergoing radiation to the chest wall and drainage areas. Although a large body of literature on the use of relaxation and massage as therapeutic interventions in various medical-care settings exists, there was a dearth of literature on the effectiveness of complementary therapies like Relaxation and Foot Massage when used for breast cancer. Moreover, published studies assessing Anxiety and Depression during radiation therapy were also rare. This study represents an effort to assess the impact of two interventions such as Simple Rhythmic Breathing Relaxation and Foot Massage on the QOL of breast cancer patients undergoing radiation to chest wall and drainage areas. The study has found various significant
differences between the control and experimental groups as well as between the experimental groups themselves. Study results suggest potential effects of both of the interventions on patients undergoing radiation therapy. To the best of the investigator’s knowledge, this study is the first of its kind especially in the Indian setting.

The major objectives for the study were the following: -

1. To describe the level of Anxiety and Depression using Hospital Anxiety and Depression Scale (HADS), in patients with breast cancer who are being treated with radiation treatment to chest wall and drainage areas

2. To describe the quality of life using Quality of Life- Breast Cancer (QOL-BC), in patients with breast cancer who are being treated with radiation treatment to chest wall and drainage areas

3. To prepare and validate the modules on two complementary therapies - Simple Rhythmic Breathing Relaxation (SRBR) and Foot Massage (FM)

4. To evaluate the effect of SRBR and FM in terms of reduction in HAD Scores (including individual factors) and improvement in QOL-BC Scores (total and various domains and factors) in patients who are being treated with radiation treatment to chest wall and drainage areas.

The study assumed that (1) Complementary Therapies are generally found to be effective methods of relaxation and so the selected complementary therapies will promote relaxation, (2) HADS and QOL-BC are valid measures of the respective concepts when used in Indian setting and (3) Treatment conditions (environment- temperature, light, noise level, odors and comfort) are essentially the same for all subjects.

The study also attempted to examine the following Hypotheses at the 0.05, or above level of significance:-

$H_1$: There will be significant reduction in the mean Anxiety scores of subjects who receive Simple Rhythmic Breathing Relaxation (R Group)
and Foot Massage (FM Group) compared to those without intervention (C Group)

H2: There will be significant reduction in the mean Depression scores of subjects who receive Simple Rhythmic Breathing Relaxation and Foot Massage compared to those without intervention.

H3: There will be significant increase in the mean QOL-BC scores of subjects who receive Simple Rhythmic Breathing Relaxation and Foot Massage compared to those without intervention.

H4: The effectiveness in reducing mean Anxiety/Depression scores by Simple Rhythmic Breathing Relaxation Technique will be different than that of the effectiveness of Foot Massage Technique.

H5: The effectiveness in increasing mean QOL-BC scores by Simple Rhythmic Breathing Relaxation Technique will be different than that of the effectiveness of Foot Massage Technique.

H6: Simple Rhythmic Breathing Relaxation / Foot Massage has got effect by itself in reducing mean Anxiety/Depression scores and thereby in increasing QOL-BC mean score.

H7: The effect of Simple Rhythmic Breathing Relaxation and Foot Massage will be different in all the 4 domains—Physical, Psychological, Social and Spiritual.

H8: There will be correlation between (a) Anxiety scores and Depression scores, (b) HAD scores and Physical domain and (c) Physical domain and the other 3 domains—Psychological, Social and Spiritual irrespective of the mode of intervention.

In the present study the two different interventions—(i) Simple Rhythmic Breathing Relaxation and (ii) Foot Massage—were tried out on Breast Cancer Patients to reduce their anxiety and depression and thereby to increase their level of quality of life (QOL). Thus the study aimed at the
determination of comparative effectiveness of the two interventions compared to the non-intervention group.

The study followed a non-equivalent control group quasi-experimental design involving three groups (i) C Group (Control - non-interventional) (ii) R Group and (iii) FM Group. It was conducted as a prospective study by assessing at 3 different time intervals, designed as Pre, Post 1 and Post II assessments. The setting of the study was the inpatient clinical field of Regional Cancer Center, Trivandrum. The population for the study was all the breast cancer patients admitted for radiation therapy to the chest wall and drainage areas, during the study period. The total sample size was 90 subjects; allocated randomly into the three groups.

The conceptual framework of the study was derived from the quality of life model applied to breast cancer (QOL-BC), developed by Ferrell, Dow and Grant (1995) that depicts the QOL domains of physical well being, psychological well being, social concerns and spiritual well being and the individual the factors by incorporating Anxiety and Depression. It was also based on the concepts on complementary therapies and the application of nursing process.

Three instruments were used for the data collection (1) A socio-demographic and disease profile, developed by the investigator, to describe the sample (age, religion, marital status, education, occupation, family monthly income and place of residence) and disease-related characteristics (stage of cancer, intake of chemotherapy and duration of treatment) (2) The Hospital Anxiety & Depression Scale (HADS) developed and standardized by Zigmond and Snaith (1983) and (3) Quality of Life - Breast Cancer Version (QOL-BC) developed and standardized by Ferrell, et al (1995). The Content Validity of the Malayalam versions both these tools were established by test retest and the Reliability by Spearman's Rank Correlation methods. The content validity of the two intervention modules—Simple Rhythmic Breathing Relaxation (SRBR) and Foot Massage (FM) prepared by the investigator were also tested and their Reliability were established by inter-rater reliability scoring method.
A pilot study was carried out on ten subjects (five for SRBR and five for FM) with breast cancer, undergoing radiation to the chest wall and drainage areas. The data were collected from 10th February 2000 to January 2001. On Day 1, after the first course of Radiation Therapy, the socio-demographic and disease profiles were collected from the subject as well as from the hospital record file. After a restful environment was established each subject was pre-tested with the HADS & QOL-BC, at baseline, before the first intervention. The R and FM groups received Simple Rhythmic Breathing Relaxation / Foot Massage respectively for 7 consecutive days whereas the C group received no experimental interventions but only routine care. The person who administered the questionnaire was not aware of the intervention to which subjects were allocated. The subjects were post tested with the same tools on Day 2 (before the second intervention) and on Day 7 (after the last intervention). The investigator herself administered the interventions. All the subjects received the intervention without reporting any side effects.

The data gathered were analyzed based on the objectives of the study and hypotheses being tested. Both descriptive and inferential statistics were used. The descriptive statistics included mean, median, frequency, mean difference, SD and so on. The inferential statistics used to test the hypotheses were Chi-square test, Student ‘t’ test, ‘F’ test /ANOVA (Analysis of Variance), Paired ‘t’ test and Correlation Coefficient ‘r’. In this way, the changes in Anxiety & Depression and QOL-BC domains/factors were analyzed and the results obtained were discussed with those from published literature.

The major findings of the study were the following: -

**DEMOGRAPHIC PROFILE**

The breast cancer patients studied were mostly in the age group ‘40-69’ years and the mean age was estimated as 47 years. Numerically the Anxiety and Depression mean score was more among women in ‘40-49’ years (12.03) compared to ‘above 50 years’ group (10.5) but was not statistically significant. Also mean QOL-BC score was 42.67 in ‘below 40 years’ age
group compared to 43.92 among women in ‘60-69 years’. This difference too happened to be due to chance factor.

Every 3 out of 4 patients included in the study were housewives. Almost 50% of the women belonged to poor socio-economic status (Rs< 1000). There were 48 women (53.3%) from the rural and the remaining 42 (46.7%) belonged to semi-urban/urban area. No appreciable difference noted in the HAD/QOL-BC scores between rural and urban population.

Also, no statistically significant difference noted in the mean HAD/QOL-BC scores between different age groups, education, occupation, place of residence and in all the 4 domains of QOL –BC except in ‘Spiritual’. It was seen that all the 3 groups – Control, FM and R - were identical prior to intervention with respect to various demographic characteristics.

**DISEASE PROFILE**

The study was taken up by giving adequate representation to different stages of cancer and about 50% of the women studied were in advanced stage of cancer. Among all the subjects, 60% were having history of exposure to chemotherapy. The mean duration of treatment prior to entering into the study was estimated as 1.33 years, which ranged from 0.25 to 13 years. While the mean HAD scores were compared with respect to Disease profile too, no statistically significant difference observed invariably in all the factors like chemotherapy status, duration of treatment and stage of cancer. In the case of QOL-BC scores an elevated Physical score was noted among patients in stage I and II but was similar in all other domains.

**INTERGROUP COMPARISON-HAD SCORES/ FACTORS**

Prior to intervention, the mean Anxiety score ranged from 10.1 to 12.5, which showed a decline of 2.7 in R group and 1.7 in FM group during post assessment I and then to 4.7 and 2.77 respectively during post assessment II (P < 0.001). The increased effectiveness noted in R group turned out to be highly significant (P < 0.001).
The pre-assessment depression score ranged from 8.2 to 10.9 in the 3 groups. During post-assessment I and II there was significant improvement in R and FM groups; the maximum being in R group (P < 0.001). All the HAD factors too, showed statistically significant reduction in the intervention groups by the end of post-assessment II except in the case of F8 ‘feel slowed down’.

**INTERGROUP COMPARISON-QOL-BC DOMAIN /FACTORS**

**PHYSICAL WELL BEING**

In the Physical domain, the mean QOL-BC scores increased to 49.7 during post-assessment I and to 57.0 during post-assessment II in R group in place of 44.9 and 57.4 respectively in FM group (P < 0.01). Thus R showed an improvement of 10.7 in place of 8.47 in FM during post-assessment I and 18 in place of 20.97 during post-assessment II. Regarding Physical domain factors, the improvement was statistically significant in all factors during post-assessment II. Numerically FM was found to be better than R group in the effectiveness in Physical domain.

**PSYCHOLOGICAL WELL BEING**

The Control group continued deterioration in Psychological well being domain throughout the intervention period. But R group showed a mean increase of 19.6 and 31.5 during post-assessment I & II respectively. In fact FM showed numerically better improvement since it showed a mean increase of 24.2 and 44.8 respectively. So even in Psychological domain Foot Massage was slightly superior to Relaxation technique. If the Psychological factors were compared statistically significant improvement was noted in all factors except in F15 ‘ability to concentrate’ and F20 ‘Distress from chemotherapy’.

**SOCIAL CONCERN**

While considering the Social concern domain scores, R group had a mean improvement of 3.07 compared to 5.5 in FM during post-assessment I. During post-assessment II it increased to 10.3 in R group and 11.7 in FM group. So numerically there was better improvement in FM. If the Social
domain factors were taken into account, statistically significant increase was observed invariably in all factors except in F 32 ‘support from others’ and F 39 ‘financial burden’.

**SPIRITUAL WELL BEING**

Even in Spiritual well being domain, the mean score reduced further during post assessment I & II. At the same time, it increased to 54.87 and 57.40 in R group and 54.87 and 57.40 in FM group during post assessment I & II respectively. Numerically the improvement in spiritual well being scores was slightly more in R group compared to FM group contrary to the effect in other domains. In this case R group showed an increase of 6.33 in place of 5.43 in FM group during post assessment II. So R group can be considered as slightly better in increasing the QOL-BC in the Spiritual domain. All the spiritual domain factors showed statistically significant improvement compared to the control group during post assessment II.

**WITHIN GROUP COMPARISON- HAD / QOL-BC SCORES**

**FM GROUP**

Regarding the effectiveness of Foot Massage, the Anxiety score reduced to 8.40 during post assessment I and then further reduced to 7.33 during the post assessment II from the pre-assessment value of 10.10. In either assessment the improvement was highly statistically significant ($P < 0.01$). Similarly the Depression score reduced to 7.40 and 6.60 respectively from pre-assessment mean of 8.20. During post assessment II, the improvement turned out to be significant at 5% level. Even if the HAD factors were considered, the reduction was significant in the case of F3 ‘frightened’, F6 ‘feel cheerful’ and F11 ‘feel restless’. Thus the intervention-Foot massage – was found to be effective in reducing Anxiety and Depression.

While considering the QOL-BC scores there was highly significant improvement during post assessments I & II in all the domains, except in the case of Spiritual domain during post assessment I. Regarding Physical domain factors, there was highly significant increase in all factors except F6
'Problem with vaginal dryness'. Similarly, almost all psychological factors also, showed highly significant improvement (P < 0.01). At the same time in the case of Social domain F 32 ‘support form others’, F33 ‘interference in personal relationship’, F38 ‘concern for female relatives’ and F39 ‘financial burden’, no statistically significant improvement noted even during post assessment II. While considering the Spiritual domain only 3 factors viz. F42, F45 and F 46 happened to be significant statistically. Thus the intervention ‘FM’ was found to be effective in reducing HAD scores and for increasing QOL-BC scores, the group as a whole as well as individual HAD/QOL-BC factors.

WITHIN GROUP COMPARISON- HAD / QOL-BC SCORES

R GROUP

In the case of R group, Anxiety & Depression showed highly significant reduction not only during Post assessment I but also during post assessment II. The mean anxiety score came down to 9.80 during post assessment I and then to 7.63 during post assessment II from the pre assessment value of 12.50. Similarly the Depression score reduced to 9.50 and 2.38 respectively from the pre assessment value of 10.90. These reductions happened to be highly statistically significant (P<0.01).

Regarding HAD Factors; there was reduction invariably in all factors except F4 ‘can laugh’, F7 ‘can sit at ease/feel relaxed’, and F12 ‘look forward with enjoyment’.

While considering the QOL-BC domain Factors, SRBR was effective (P<0.01) in all 4 domains including Spiritual domain. If the specific QOL-BC factors were considered SRBR was found to be effective in all factors during post assessment I & II except in F6 and F7 during post assessment I with regard to Physical domain. Even the Psychological factors showed significant reduction during post assessment II in all factors except F15 ‘ability to concentrate’. In this case SRBR showed only limited effectiveness during post assessment I. At the same time the Social concern domain showed significant improvement during post assessment I & II in most of the factors.
It was rather effective in more than 50% of the Spiritual domain factors as well. Thus SRBR was also found effective in bringing down the HAD scores and to increase the QOL –BC domains/Scores.

**INTER DOMAIN EFFECTIVENESS**

The inter domain effectiveness of the two interventions was compared taking the total quality of life in each domain as 1 or 100%. No significant difference was noted in all 4 domains 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 I there was significant increase in all 4 domains of the intervention groups. During post assessment II, FM and R groups showed maximum improvement in Physical domain while the minimum being recorded in the Spiritual domain.

**CORRELATION BETWEEN ANXIETY & DEPRESSION /QOL-BC**

While considering the correlation between QOL-BC domains there was strong positive correlation between Physical domain scores and other domains. At the same time, if the HAD scores were decreased there was a proportionate increase in the QOL scores (negative correlation). On the other hand if Anxiety scores were increased, the Depression scores were also increased (positive correlation). Hence it was derived that Physical domain was the major domain that had positive correlation with the other domains and negative correlation with Anxiety & Depression.

**CONCLUSIONS**

The following conclusions are drawn on the basis of the data analysis.

1. Breast Cancer patients undergoing radiation to the chest wall and drainage areas generally show an increase in anxiety and depression and thereby decrease in their quality of life.
2. Simple Rhythmic Breathing Relaxation (SRBR) and Foot Massage (FM) showed statistically significant reduction in the Anxiety and Depression and a significant increase in the QOL scores.

3. The Anxiety and Depression scores in R group showed better reduction compared to FM group during post assessment I & II.

4. With regard to the QOL scores, both the interventions (SRBR & FM) had similar significant improvement statistically. However, numerically FM group had slightly better improvement.

5. In both the interventions, the effectiveness showed an increasing trend if the period of intervention was increased.

6. Simple Rhythmic Breathing Relaxation (SRBR) and Foot Massage (FM) showed decline in HAD scores and increase in the QOL scores, not only in the case of mean total scores but also in various factors taken for the assessment.

7. The ‘within group’ comparison of R group showed very high level of significance in the reduction of HAD scores and increase in the QOL scores.

8. The ‘within group’ comparison of FM group also showed very high level of significance in the reduction of HAD scores and increase in the QOL scores.

9. In the ‘inter-domain comparison’ the maximum effectiveness of the two interventions was reflected in the physical domain and the minimum in the spiritual domain.

10. There was strong positive correlation between Anxiety and Depression. In other words, if the Anxiety is increased, Depression is also increased.
11. There was strong negative correlation between HAD scores and QOL scores, i.e., if the Anxiety and Depression are decreased, QOL scores is increased.

12. There was strong positive correlation between the domain scores. In other words, if the physical domain scores are increased, there was a corresponding increase in the other domains except in the case of spiritual domain.

13. Since Simple Rhythmic Breathing Relaxation (SRBR) showed better improvement in Anxiety and Depression, it is advisable for the breast cancer patients with an initial increased HAD scores.

14. Since Foot Massage appeared to be better for providing increased effectiveness in improving QOL, it is advisable for the breast cancer patients with minimum initial HAD scores and QOL scores.

IMPLICATIONS OF THE RESULTS

Breast Cancer is a disease, which affects not only the physical but also the psychological, social and spiritual aspects of the women. The results of the study clearly indicate the role of simple complementary therapies, which can be administered by nurses in cancer units/hospitals. The nurses who look after such patients can play a significant role in alleviating many of the above-mentioned problems. At present the quality of life of the patients undergoing RT for breast cancer is comparatively very low due to which they are anxious, sleepless and tensed. Since the study is found to be effective, the same complementary therapies can be implemented in a wider group through which better QOL can be achieved.

NURSING PRACTICE

The Nursing practice has to keep pace with the changes that are being taken place in the disease spectrum of the population. Appropriate and feasible modifications have to be incorporated to maximize the nursing care. The relevance of the study would be its potential to modify nursing practice,
which should go beyond physical care. The complementary therapies (SRBR & FM), that have been studied are easy to learn and are neither machine dependent nor technology oriented. These are simple, can be easily practiced by nurses with minimum training, they do not need extra expenditure and are acceptable to the patients, which can be carried out in the outpatient setting and they help to provide necessary psychosocial and physical support to patients who are otherwise left alone on their own. These are more applicable in cancer hospitals when patients are waiting for long hours in the various sections such as radiation therapy, chemotherapy and so on.

Nurses are in contact with patients who have breast cancer at all stages of the disease and treatment, because they meet the women in the hospital, at the out patient clinic and in their homes. They play an important role in meeting the needs of these women. Hence, nurses should include complementary therapies in their nursing practice, which will improve their professional satisfaction as well as the nurse-patient relationship.

NURSING EDUCATION

The disease profile of the population is constantly changing and hence nurses who are in the forefront of patient care have to keep themselves constantly updated to meet the ever-increasing demands. In chronic diseases like breast cancer, the patient goes through a lot of symptoms that are beyond routine medical care. Complementary Therapies such as Simple Rhythmic Breathing Relaxation (SRBR) and Foot Massage (FM) are forms of alternative medicine that can be taught to nursing students.

NURSING RESEARCH

Nursing in the Indian scenario has been generally concentrated on giving medicines and injections and carrying out doctors’ orders and assisting in operation theatres. The nursing practice has to evolve new health models and new levels of care and this can be achieved only through continuous research activities. The present work demonstrates how meaningfully and usefully research programmes can incorporate such interventions in routine nursing practice. Similar programmes should be undertaken in various
settings so that the nurses are made aware of research methods as well as improve their professional capacity all of which will ultimately improve quality patient care.

**LIMITATIONS OF THE STUDY**

The findings of the study should be weighed against its limitations. The following limitations should be considered regarding the current study:

1. The investigator confined her study only to the subjects who were admitted in Regional Cancer Centre.

2. Since the interventions were carried out only during patient’s hospitalization, long-term results are not known.

3. The sample size (30 in each group) is not large enough for generalizations though the sample size is adequate statistically.

4. The results are based on only three assessments within a period of 7 days. The post assessment III, which was planned on Day 30, could not be carried out, as the follow up attendance of the subjects was not adequate.

5. There was no randomization of the subjects initially. During the initial stage, 90 subjects were selected by non-probability purposive sampling and it limits the generalizability.

6. The investigator could not control other treatments, if any, received by the subjects during the intervention period.

7. The two Complementary therapies can be practiced effectively in hospitals with good surroundings and with adequate space and other facilities as the Regional Cancer Centre, Trivandrum, where the study was conducted. Given the conditions of various hospitals it is not sure whether this can be practiced everywhere.
RECOMMENDATIONS

Breast cancer is a disease which needs a multi dimensional approach. Based on the findings of the present study, with its limitations, the following recommendations can help to improve the quality of life of the Breast cancer patients through good nursing practices: -

1. It is recommended that the complementary therapies (SRBR & FM) which have been tested and found useful in this study can be introduced into nursing practice with minimal training of nurses, minimal infrastructure modification and with much less resources for caring breast cancer patients.

2. Standard protocols for complementary therapies should be made available in the caring units for the nurses.

3. Nurses must be trained to utilize different varieties of complementary therapies.

4. Nurses should address and understand the psychosocial and emotional problems by communicating with the patients.

5. Nurses can identify the patients who are distressed and tensed and can provide relaxation techniques to help them to overcome the same.

6. Nurses can undertake similar research programmes which will improve their academic and research capabilities, so that they can identify feasible low cost alternative interventions.

7. Nursing Education must integrate complementary therapies as important components in the management of any terminally ill patients, and not only cancer patients

8. Study may be replicated with combined complementary therapies such as guided imagery, aromatherapy, music therapy or art therapy on patients with different types of cancer, for better effect.
9. The study has emerged another hypothesis that the R group has significantly reduced anxiety and depression than that is anticipated. It is recommended that this hypothesis may be further studied on a bigger sample.

10. Nurses should plan for ways of improving nursing practice by including complementary therapies at different stages of the illnesses.

11. Nurses, who use Relaxation therapy and Foot Massage on their patients may, maintain objective anecdotal records of their experiences, including the length and frequency of treatments and patient experiences.

12. Replication of the same study on a larger sample to draw more definite conclusions may be planned.

13. Further prospective cohort studies must be taken up to assess the effectiveness of these interventions in a long-term perspective.

The present study, to the investigator’s knowledge, is the first ever reported intervention study of its kind, among the breast cancer patients. The Complementary therapies (Simple Rhythmic Breathing Relaxation (SRBR) and Foot Massage (FM), which have been tested and found useful in this study, can be introduced into nursing practice with minimal training of nurses, minimal infrastructure modification and with minimal resources, thereby it helps in improving the quality of life of the breast cancer patients undergoing radiation to chest wall and drainage areas.