CHAPTER III
METHODOLOGY

This chapter provides a brief description of the method adopted by the investigator in the study that was designed to determine the effectiveness of meditation on depression and QoL among women with breast cancer subjected to mastectomy. This chapter deals with the framework or guide used for the planning, implementation, and analysis of the study. It basically provides an outline of how the research will be carried out and the methods that will be used. It includes the description of the research design, dependent and independent variables, sampling design and a planned format for data collection, analysis and presentation.

3.1 RESEARCH DESIGN

The research design adopted for this study was quantitative quasi experimental non-randomized with the components of manipulation, non-randomization and control. The aim of the study was to determine the effectiveness of meditation on depression and QoL among women with breast cancer subjected to mastectomy.

Table 2. Schematic representation of research design

<table>
<thead>
<tr>
<th>Groups</th>
<th>Pretest</th>
<th>Intervention(s)</th>
<th>Posttest I</th>
<th>Posttest II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study</td>
<td>0₁</td>
<td>* X</td>
<td>0₂</td>
<td>0₃</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>30th day</td>
<td>90th day</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(28,29,30,31,32)</td>
<td>(88,89,90,91,92)</td>
</tr>
<tr>
<td>Control</td>
<td>0₁</td>
<td>*</td>
<td>0₂</td>
<td>0₃ X₁</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>30th day</td>
<td></td>
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</tbody>
</table>
Keys

NR - Non –Randomized Samples

01, - Pretest (Depression and QoL )

02,03  - Posttest assessment (Depression, QoL and meditation performance)

* - Routine care

X - Video assisted teaching

- Enaction under supervision 1 day prior to surgery, 2nd and 3rd post operative day

- Reminder every fortnight

X1 –Video assisted teaching followed by enaction after posttest II assessment

Manipulation

Manipulation refers to the meditation that was provided by the investigator to the women with breast cancer subjected to mastectomy in the study group along with routine care. The video assisted teaching on meditation was shown by the investigator to the women one day prior to surgery, second and third post-operative day on one to one basis for 25 minutes duration and it was enacted under the supervision of the researcher within the duration of 40 minutes. Queries related to meditation were clarified. The video assisted teaching on meditation included meaning, purposes, types and uses of basic and nine centers meditation. The basic meditation included were agna, moolathara and thuriya. The nine centers meditation includes moolathara, swathitana, maniporaga, anagatha, vishukthi, agna, thuriya and thuriyathetha. On the third post-operative day the performance diary on meditation was handed over to the patient to perform meditation at home. The investigator
reminded the women every fortnight through telephone. The performance of meditation was evaluated through checklist during first month and third month follow-up.

**Activities of Manipulation**

- Video assisted teaching on meditation was shown to the women on one to one basis one day prior to surgery, second and third post-operative day
- Meditation was enacted by the women under the supervision of the investigator on one to one basis one day prior to surgery, second and third post-operative day
- Meditation diary was handed over to the patient on the third post-operative day
- The reinforcement through telephone was given every fortnight consistently
- The meditation checklist was used to assess the patients performance during first month and third month follow up.

**Control Group**

The women in control group received routine care given by the health team members in the clinical setup. The investigator interacted with the group about their general health. The video assisted teaching on meditation was shown to the women after the third month post-assessment.
3.2 Setting

The study was conducted among women with breast cancer subjected to mastectomy admitted in **Sri Ramachandra Hospital and Research Institute (SRMC)** and **Adyar Cancer Institute (WIA)** at Chennai.

**Sri Ramachandra Hospital and Research Institute (SRMC)** is a tertiary care multi-specialty hospital. The institution founded as a teaching hospital of Sri Ramachandra Medical College and Research Institute with the intention of translating the experience and expertise in medical education into tangible and affordable health care to the community. Today, SRMC is a leader in health care delivery in South India providing cutting edge state-of-art care for patients who walk through its portals daily. The hospital is multi-specialty with some of the best doctors in the country. It has got 1740 beds, out of which 25 beds are allotted for oncology. The women with breast cancer were admitted for surgery in general, special, private, semi private and deluxe wards. On an average in a period of 15 days, approximately two or three patients are posted for mastectomy and it also depends on admission. The patients consult a doctor based on appointment and chose the ward as per their affordability. There are seven units under the department of surgery. Each day one unit takes up the functioning of the Operation Theater and after surgery the patient is shifted to post-operative wards. The detailed orientation about the ward is given by the nurse. Pre-operative preparation is carried out on the day prior to surgery.

**Cancer Institute Adyar (WIA)** CIA is a research centre, a centre of preventive oncology, and a College of Oncology Sciences (a postgraduate college that conducts super-specialty courses). Its centre for preventive oncology has been working in conjunction with non-government organizations and government hospitals
to conduct cancer screening camps. Annually, more than 95,000 to 100,000 patients from all parts of India visit the hospital; hardly 0.5% of whom are covered by health insurance. People depend on the Adyar Cancer Institute, where treatment is either free or subsidized. The Institute has 423 beds, of which 297 are for free treatment. The women with breast cancer are admitted on Madhuram Narayanan special wards, Patel ward and free wards.

3.3 Population

The accessible population included the women who had breast cancer subjected to mastectomy and sought medical help at inpatient department of Sri Ramachandra Hospital and Cancer Institute Adyar, Chennai. The target population included for this study was women with breast cancer between the age of 21-60 years, at stage I or II or IIIa as per TNM classification and also subjected to mastectomy during the study period.

3.4 Sample

Women diagnosed with breast cancer subjected to mastectomy and those who fulfilled the inclusion criteria and those who available during data collection period from March 2010 to Oct 2011 in Sri Ramachandra Medical College and Cancer Institute Adyar, Chennai.

3.5 Sample Size

The sample size was collected using the formula.

\[ n = \frac{2(Z\alpha + Z_{1-\beta})^2 \sigma^2}{\Delta^2} \]
Sample size was determined using power analysis and effect size. The study involves comparison of two means. A total of 140 subjects were needed to achieve the significance of 0.05 and a power of 0.74 for a 50% reduction in the total depression score (Lengacher, 2001). The investigator considering the possibility of dropouts decided to enroll 10% of excess sample for the study. Hence the sample constituted of 150 subjects in each group. The researcher rounded up the size of the total sample to 300. Three hundred women with breast cancer gave concern to participate in the research in the period of one and half years. During the two years data collection period, 150 in study group and 150 in control group were selected through purposive sampling technique.
3.6 Sampling Technique

Three hundred subjects who fulfilled the inclusion criteria, during the period of study were considered as a samples

![Flow chart of participants’ recruitment and follow-up](image)

**Figure 2. Flow chart of participants’ recruitment and follow-up**
3.7 Criteria For Sample Selection

1. Inclusion Criteria

Women who were

- in the age group of 21-60 years
- diagnosed with breast cancer of either stage I or II or IIIa as per TNM classification
- with minimal, mild or moderate depression
- with the ability to understand Tamil or English
- planning a mastectomy within a week
- under the radiation or chemotherapy

2. Exclusion Criteria

Women who were

- practising any type of meditation
- with any cognitive impairment
- with sensory deprivation
- had mastectomy

3.8 Development and Description of the Tool

Extensive review of literature, discussion and views of experts from the field of psychiatry, surgical oncologist, nursing, clinical psychology and complementary therapy were considered for the development of tool. The tool consists of six parts.
3.8.1 Part I – Background Variables

The tool was developed by the investigator to collect data on demographic variables and clinical variables (Appendix D1) and Tamil version of background variable was used in the study (Appendix D2). It consisted of two sections

**Section A:** Demographic variables include age, residence, educational status, marital status, occupation, family income/month, religion and types of family.

**Section B:** Clinical variables of the women with breast cancer subjected to mastectomy include period of illness, stages of cancer and types of treatment.

**Scoring and Interpretation**

Score was not allotted. The data were used for descriptive analysis.

**Administration**

The background variables questionnaire were answered by women with breast cancer subjected to mastectomy during pretest.

3.8.2 Part II - Beck Depression Inventory- II (BDI-II)

The standardized tool was constructed by Aaron T. Beck, Gregory K. Brown, and Robert A. Steer (1996) (Appendix-D3). The BDI-II was used to analyze the severity of depression responses from women with breast cancer subjected to mastectomy. It is a 21 symptoms multiple choice self rated questionnaire with each item rated with a set of four possible answer choices of increasing severity. When the test is scored, the value of 0-3 is assigned for each answer and the total score is compared to a key to determine the severity of the depression. It can be administered for adults and can be completed within 10 minutes. BDI-II is freely available for the
primary health care uses in India. It consists of symptoms of depression such as sadness, pessimism, past failure, loss of pleasure, guilt feelings, crying, suicidal thoughts or wishes, self-criticalness, self-dislike, punishment feelings, agitation, loss of interest, indecisiveness, worthlessness, irritability, changes in appetite, loss of energy, concentration difficulty, tiredness or fatigue, loss of interest in sex and changes in sleeping patterns. The Tamil version of BDI-II was used in the study (Appendix- D4). The score interpretation is as follows;

**Scoring and Interpretation**

The total score was 63. The level of depression was interpreted as follows:

1-13 - Minimal depression

14-19 - Mild depression

20-28 - Moderate depression

29-63 - Severe depression

The women were asked to report their feeling over the past 2 weeks. It contains a four point scale for each item. BDI-II is a self-report analysis of depressive symptoms. The BDI-II serves as an indicator of the occurrence and severity of the symptoms of depression. Women scoring minimal (1-13), mild (14-19) and moderate (20-28) were only included for the study.
**Administration**

The BDI-II questionnaire were answered by women during pretest, posttest I and posttest II. Subjects were asked to report about the symptoms they faced based on their past two week’s experience.

**3.8.3 Part III – QoL – Breast Cancer Version**

The tool was prepared by National Medical Center and Beckman Research Institute. Tool can be useful in clinical practice as well as for research. It is a 46 item ordinal scale that measures the QoL of a breast cancer patient (Appendix- D₅ ) representing the four domains including physical wellbeing, psychological wellbeing, social wellbeing and spiritual wellbeing. The scoring is based on a scale of 0 to 10 which ranges from worst outcome to best outcome. For example, if a subject circles “3” on such an item, (10-3 = 7) thus the recorded score is 7. Several items have reverse anchor to score. The reversed items are 1-7, 9-10, 17-29, 33-39 & 43. The positive scores are 8, 11-16, 30, 32, 40-42 and 44-46. It was modified as 40 items; the following items were not applicable in the study: Q. no.23) Completion of treatment, Q. no. 26) Future diagnostic tests, Q. no. 27) A second cancer, Q. no. 28) Recurrence of cancer, Q. no.29) Spreading (metastasis) of your cancer, and Q. no. 30) To what degree do you feel your life is back to normal? The Tamil version of QoL used in this study (Appendix- D₆ ).
Scoring and Interpretation

Total score 400 was interpreted as follows

1-80 - Very poor
81-160 - Poor
161- 240 - Average
141- 320 - Good
321- 400 - Very Good

Administration

The patient is asked to read each question and decide if she agrees with the statement or disagrees. The patient is then asked to circle a number to indicate the degree to which she agrees or disagrees with the statement according to the word anchors on each end of the scale. The questionnaire is distributed to the women during pretest, posttest I (one month) and posttest II (three month).

3.8.4 Part IV- Meditation Intervention

Video on meditation was prepared by the investigator on consultation with experts. It consists of meaning, types, uses and techniques of meditation including **Basic** (Agna, Moolathara and Thuria) and **Nine Centres Meditation** (Moolathara, Swathitana, Maniporaga, Anagatha, Vishukthi, Agna, Thuria, Thurithedha and Thuvathasangam). They were explained through video presentation which was of 25 minutes duration in Tamil and 23 minutes in English. Then it was enacted by the subjects under the supervision of the investigator. So each individual session was 40 minutes. A total of six sessions were practised by the subjects under the supervision of the investigator. The intervention was administered one day prior to surgery followed by enaction on the same day under the supervision of investigator. It was also followed during the 2nd and 3rd post-operative day.
3.8.5 Part V- Meditation performance check list

The checklist (Appendix- D7) was prepared by the investigator for only the study group to measure the performance of the subjects. The checklist has 20 items with the option of dichotomous response like yes/ no. It consisted of 8 prerequisite guidelines and 12 core guidelines. The Tamil version of performance checklist was used (Appendix- D8). It was used during posttest I and II a total of three basic techniques in basic meditation and eight techniques include nine center meditation represented as core guidelines shown as follows

**Core Guidelines**

Focus your eyes in between the eyebrows (AGNA-3mins)

Concentrate on the bottom of spinal cord (MOOLATHARA-3mins)

Concentrate on the middle of the head (THURIA-3mins)

Nine centre meditation: Concentrate on

- The bottom of spinal cord (MOOLATHARA-3mins)
- Four fingers below the umbilicus (SWATHITANA-3mins)
- Umbilicus (MANIPOORAGA-3mins)
- The centre of the chest (ANNAGATHA-3mins)
- The throat (VISUKTHI-3mins)
- In between the eyebrows (AGNA-3mins)
- Middle of the head (THURIA-3mins)
- One feet above head (THURIATHETHA-3mins)
**Scoring and Interpretation**

Total score was 20 it was analyzed through descriptive statistics. If they answer ‘yes’ the score was ‘1’ and if ‘no’ the score was ‘0’. It was categorized under prerequisite and core guidelines.

**Administration**

The meditation performance checklist was administered by the investigator on the 30\textsuperscript{th} day and 90\textsuperscript{th} day during post intervention period for study group.

**3.8.6 Part VI- Meditation performance diary**

Daily performance diary (Appendix- D\textsubscript{9}) was maintained by the study participants. It consists of the vertical column from the first day to 30\textsuperscript{th} or 31\textsuperscript{st} day of the month and horizontal column consists of performance and whether experienced relaxation or not. The diary was prepared by the researcher and the Tamil version also (Appendix- D\textsubscript{10}). Participants were requested to maintain the relaxation diary after the performance. The researcher described the daily performance diary taught how to record and every fortnight the researcher reminded the participants about keeping the diary. Study group participants maintained the diary throughout the study period.

**Scoring and Administration**

The diary distributed to women during 3\textsuperscript{rd} post-operative day mainly focused on whether they practiced properly and improved their skill in meditation. The women were requested to maintain the diary every day and they had to bring it during the first and second posttest.
3.9 Validity and Reliability of the Tool

The content validity was obtained from experts in the fields of Nursing, psychiatry, surgical oncology, clinical psychology, research experts and yoga practitioner (Appendix-E). The reliability of the tool was established by conducting pilot study to assess the feasibility to conduct the main study.

3.9.1 Beck Depression Inventory-II (BDI-II)

It’s a standardized tool with established validity. The reliability of the BDI-II tool was translated into Tamil. The Tamil version of BDI-II was subjected for reliability with test-retest method. The ‘r’ value obtained was 0.94 (positive correlation).

3.9.2 QoL- Breast Cancer Version

It is a standardized tool with established validity. The adapted tool was translated into Tamil. The Tamil version of the modified QoL was subjected for test-retest reliability method. The ‘r’ value obtained was 0.93 (positive correlation).

3.9.3 Meditation performance checklist

Meditation performance check list reliability was checked by using interrater method. The interrater observer along with investigator was also trained in the meditation practice and was familiar with meditation practices used for the study. The obtained ‘r’ value was 0.81 (positive correlation).

These tools were found to be reliable and valid and they were used further to proceed with the data collection for the study.
3.10 Meditation intervention

It refers to the interactive teaching learning session (Appendix- D11). It was designed by the researcher and reviewed by two experts in this area. The investigator explained about the meditation and samples were seated in comfortable position to watch the video. It consisted of the meaning, types, uses and techniques of meditation including Basic (Agna, Moolathara and Thuria) and Nine Centres Meditation (Moolathara, Swathitana, Maniporaga, Anagatha, Vishukthi, Agna, Thuria, Thurithedha and Thuvathasangam). Then it was enacted by the subjects under the supervision of the investigator. The intervention was administered one day prior to surgery followed by the enaction on same day under the supervision of investigator. It was also followed during the 2nd and 3rd post-operative day.

The video session shown to the women with breast cancer lasted for 25 minutes in Tamil (Appendix- D12) and 23 minutes in English. The objectives of the content included are as follows

- Understand the meaning of Meditation
- Describe the benefits of meditation
- Enumerate the types of meditation
- Demonstrate leg exercise for the women with breast cancer subjected to mastectomy
- Develop beginning skill while doing meditation

The following picture represents the Basic and Nine Centers Meditation
3.11 Pilot study

A pilot study was conducted during month of 2009 January to November 2009 at Sri Ramachandra Hospital. The permission was obtained from the Dean of Faculties, Medical Director and Medical Superintendent to conduct the pilot study. It was conducted to ensure the validity and reliability for providing the intervention. The pilot study results proved the feasibility of the study. Some modifications were made in the tool after the pilot study based on the experts opinion.

Modifications done after pilot study

In QoL- Breast Cancer Version question number 23, 26, 27,28,29,30 were removed. The women with breast cancer subjected to mastectomy at present were on the process of treatment so Q. no.23) Completion of treatment was removed. The Q. no. 26) Future diagnostic tests were detached because, they did not have future plan to go for diagnostic test during the study period. As per the criteria of the study the women should have first time diagnosis of breast cancer, so Q. no. 27) A second cancer. Q. no. 28) Recurrence of cancer and Q. no.29) Spreading (metastasis) of your
cancer were impassive. The women expressed that they are already suffering from the disease, so they asked the researcher “how do we come back to our normal life?” because of this Q. no. 30) To what degree do you feel your life is back to normal? were distanced. The advisory committee suggested the researcher to take another setting in addition to Sri Ramachandra Hospital.

3.12 Ethical consideration

An approval to conduct the study was obtained from the SRU institutional ethics committee (Appendix A). The ethical consideration criteria were based on the Indian Council of Medical Research guidelines on biomedical research in human beings. The investigator obtained permission from the chairperson, Cancer Institute Adyar (WIA).

Information essential for consent included description of the purpose of the study, the research activities and the usefulness of the study outcome, assurance of privacy and confidentiality, the opportunity to answer any question that a potential subject might have, and the option to withdraw from the study at any time.

3.13 Data collection procedure

The data collection procedure was conducted from December 2009 to October 2011. The data were collected in Sri Ramachandra Hospital and Cancer institute Adyar, Chennai.
Data collection procedure for study group

1. The researcher introduced herself to the participants and obtained informed consent from those who met the inclusion criteria. The participants were selected through purposive sampling technique.

2. The women were asked to sit in comfortable position to watch a video assisted teaching on one to one basis. The pre-test was conducted among women through demographic and clinical variables, level of depression and modified QoL in study and control group before installing intervention with the help of research assistants.

3. The women were asked to sit in comfortable position to watch a video assisted teaching on one to one basis at bedside, a day prior to surgery and 2\textsuperscript{nd} and 3\textsuperscript{rd} post operative days along with routine care.

4. After watching the video assisted teaching the participant enacted under the supervision of the researcher.

5. On the third post-operative day, the investigator gave the meditation performance diary to the subjects to maintain at home to improve the skill on meditation.

6. The reminder call was given through telephone, every fortnight to the study group to reinforce the importance of practising meditation to reduce depression and improve their QoL.

7. The posttest I was conducted on 30\textsuperscript{th} day (28, 29, 30, 31, and 32) for the study group when they came for follow up and the subjects were assessed on their level of depression and modified QoL with the help of research assistants along with routine care. The participants were asked to perform
meditation to enhance their skill with the help of meditation performance checklist.

8. The posttest II was conducted on 90\textsuperscript{th} day (88, 89, 90, 91, and 92) for the study group when they came for follow up and the subjects were assessed for their level of depression and modified QoL with the help of research assistants along with routine care. The participants were asked to perform meditation to enhance their skill with the help of meditation performance checklist.

**Data collection procedure for Control Group**

The researcher introduced herself to the samples of the control group and got their consent to participate in the study. The subjects were assessed for the level of depression scale and modified QoL during pretest along with routine care.

When the subjects came for follow-up on the 30\textsuperscript{th} day (28, 29, 30, 31, and 32) their level of depression and modified QoL was measured along with routine care. For the second time, the subjects were assessed on 90\textsuperscript{th} day (88, 89, 90, 91, and 92) to check their level of depression and modified QoL along with routine care and then the video assisted teaching was showed to the control group.

Everyone was encouraged to come for the follow-up to encourage the quality of care given by the both institutions. So the researcher found no attrition in the study.
### Schematic representation of data collection procedure

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Data collection phase</th>
<th>Groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-test</td>
<td>Assessment of depression and QoL among women with breast cancer subjected to mastectomy</td>
<td>Study and Control</td>
</tr>
<tr>
<td>One day prior to Surgery</td>
<td>The video assisted teaching on meditation following an enaction under the supervision of researcher and routine activities.</td>
<td>Study</td>
</tr>
<tr>
<td></td>
<td>Routine activities.</td>
<td>Control</td>
</tr>
<tr>
<td>First post-operative day</td>
<td>The video assisted teaching on meditation following an enaction under the supervision of researcher and routine activities.</td>
<td>Study</td>
</tr>
<tr>
<td></td>
<td>Routine activities</td>
<td>Control</td>
</tr>
<tr>
<td>Second post-operative day</td>
<td>The video assisted teaching on meditation following an enaction under the supervision of researcher and routine activities.</td>
<td>Study</td>
</tr>
<tr>
<td></td>
<td>Routine activities</td>
<td>Control</td>
</tr>
<tr>
<td>30th day after Pre-test</td>
<td>Post-assessment on depression and QoL. Subjects were assessed through meditation performance checklist along with routine care</td>
<td>Study</td>
</tr>
<tr>
<td></td>
<td>Post-assessment on depression and QoL with routine care</td>
<td>Control</td>
</tr>
<tr>
<td>90th day after Pre-test</td>
<td>Post-assessment on depression and QoL. Subjects were assessed through meditation performance checklist along with routine care.</td>
<td>Study</td>
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<tr>
<td></td>
<td>Post-assessment on depression and QoL with routine care then video assisted teaching was showed.</td>
<td>Control</td>
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</tbody>
</table>
3.14 Data analysis plan
Descriptive statistics was used to arrange the data in a scientific way. Inferential statistics was used to test the hypothesis. Data were analyzed using the Statistical Package for the Social Sciences (SPSS version 16).

### Data analysis plan

<table>
<thead>
<tr>
<th>Methods</th>
<th>Type of statistics</th>
<th>Purposes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptive Statistics</td>
<td>Frequency, Percentage, Mean, SD</td>
<td>Assess the sample characteristics and study variables</td>
</tr>
<tr>
<td>Inferential Statistics</td>
<td>Paired ‘t’test</td>
<td>Compare the outcome variables before and after intervention within the group.</td>
</tr>
<tr>
<td></td>
<td>Independent ‘t’ test</td>
<td>Compare the outcome variables before and after</td>
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<tr>
<td></td>
<td>RM ANOVA</td>
<td>Assess differences in outcome over time.</td>
</tr>
<tr>
<td></td>
<td>Chi square</td>
<td>Assess the homogeneity of samples between the groups.</td>
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<tr>
<td></td>
<td></td>
<td>Associate selected background variables with selected outcome variables.</td>
</tr>
<tr>
<td></td>
<td>ANOVA</td>
<td>Associate selected background variables with selected outcome variables.</td>
</tr>
<tr>
<td></td>
<td>Pearson’s Correlation</td>
<td>Identify the relationship between depression, QoL and performance of meditation.</td>
</tr>
<tr>
<td></td>
<td>Regression</td>
<td>Regression analysis to evaluate the role of independent variables and the dependent variables.</td>
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</tbody>
</table>