CHAPTER III

Materials & Method

The purpose of this chapter is to describe the method and procedure conducted in this research study. This description includes the study aim, research questions, design utilized in this work, study setting, description of the sample, tools of data collection, procedure for conducting the study, administrative design, statistical design and limitations encountered.

Materials and method for this study are portrayed under four main designs as follows:

I. Technical design.
II. Operational design.
III. Administrative design.
IV. Statistical design.

1) Technical design

Aim of the study:

This study aims to assess the post mastectomy effects on body image, self-esteem and quality of sexual life among women with breast cancer.

Research design:

A descriptive exploratory research design was used to assess the post mastectomy effects on the body image, self-esteem and quality of sexual life among women with breast cancer.

Research question:

What are post mastectomy effects on the body image, self-esteem and quality of sexual life of women with breast cancer?

Subjects:

Convenient sample of 10% of the women attending hormonal therapy follow up at Outpatient Clinic of Oncology Center Mansoura University which amounts to 200 subjects of those who fulfill the following criteria:

1) At least after one year of mastectomy.
2) Age between 30-50 years old.
3) Married before mastectomy and still married after mastectomy.
4) Willing to voluntary participate in the study.
5) Receiving hormonal Therapy.

Setting:

This study was conducted at the outpatient clinic of Oncology Center of Mansoura University. The Oncology Center of Mansoura University was officially opened by Egyptian President in October, 1984. Its main objective is to provide comprehensive management of all types of tumors and blood diseases for all citizens in Dakahlia and Delta Governorates.

- **Main Building**

The building is composed of 13 floor son a whole area of 2500 m^2, which contain departments for inpatient and out patients' services as well as pharmacy for dispensing medications and clinical laboratories for investigations of all patients. Most of the clinical services are provided

free of charge for the majority of patients (82%), while the rest of patients are either receiving charged service as private care or as covered by insurance programs. The inpatient hospital departments serve both male and female patients. Inpatients departments contain medical, surgical, operating theaters and intensive care units to provide care for critically ill patients. In addition there are departments for serving children, for bone marrow transplantation and rooms for isolation.

- **Out-patient Clinic:**

- Consist of the following:

1) Surgical outpatient clinics: located in the first floor of the center, contain six beds for examining the patients, operation rooms including surgical endoscopies and sixteen beds (eight for men and eight for the women)for patients of one day treatment.

2) Medical outpatient clinics: located in the second floor of the center, contain six rooms for examining the patients and follow up cases, e.g. Women receiving hormonal therapy after one year of mastectomy and follow up for other oncology patients.

Working hours from eight o'clock in the morning until four o'clock in the afternoon. Provided services also include blood analysis, liver and kidney function tests, x ray, ultrasounds, sampling under ultrasound and analysis of spinal cord paracentesis.

- One day treatment department with sixteen beds capacity (eight for men and eight for women) is for daily doses of chemotherapy.

Tools for data collection:

In order to collect the necessary information for this study, four tools have been used. Two tools were developed by the investigator and two tools original standardized instruments, but undergone some modifications. In the following a brief description of these four tools.

I. **Socio-demographic, and Clinical Data Structured Interview Schedule (Appendix I):**

This tool is a structured interview questionnaire designed by the investigator in Arabic and English languages with back translation procedure to assess the following related information. The first part of this tool includes socio-demographic data of age, residence, address, duration of marriage, level of education and occupation, while the second part includes the clinical data of the studied sample which include date of mastectomy, medical and surgical history, psychological and sexual complains and receiving chemotherapy or radiotherapy.

II. **Hopwood Body Image Scale: (HBIS) (Appendix II):**

This is a 4-point Likert scale developed by **(Hopwood, P, Lee A, Shenton A, Baildam A, Brain A, Lalloo F., A; 2000&Hopwood P,Fletcher, I; Lee, A; Al Ghazal. S, 2001),** to quickly and comprehensively assess Affective (e.g. feeling self-conscious), Behavioral (e.g. difficulty looking at the naked body) and Cognitive (e.g., satisfaction with appearance) dimensions of body image in cancer patients. This tool is designed to be used with any type of cancer patients or patients receiving cancer treatment. The HBIS is composed of ten items that measure the impact of surgery on self-consciousness, physical and sexual attractiveness, femininity,

satisfaction with body and scars, body integrity and avoidance behavior.

The original scoring system uses4 point Likert rating scale ranging: from 0- (Not at all), 1- (A little), 2- (Quite a bit), 3- (very much) with a total score ranging between 0 and30 degrees as zero represent: "No symptoms or distress" and higher scores corresponding to "Increasing distress and concerns of body image". Women with score 0 to 10 have minimum concerns of their body image, while women with score 11to 20 have moderate concerns of their body image, and women with score 21 to 30 have high concerns of their body image. Translation into Arabic language was done by back translation procedure.

Reliability of the Arabic version of the tool was held on 20 post mastectomy women. Test-retest-reliability coefficient was held on the same patients by the same investigator within 14 days interval in the same setting.

Its value for the 10items was (0.93) which indicated that the Arabic version of HBIS demonstrated excellent scale reliability.

III. **Rosenberg Self-Esteem Scale: (RSES)(Appendix III):**

This is a 4-point Likert scale developed by **Rosenberg (1965),** designed for the assessment of self-esteem. The RSES is composed of ten items that concerned with the impact of surgery on general feelings of the patients about themselves, self-respect, self-worth, satisfaction and their qualities.

The original scoring system used 4point Likert rating scale, ranging as follows : 0- (Strongly disagree), 1- (Disagree), 2- (Agree), 3- (Strongly agree) with a total score ranging between 0, and 30 degree with 0 indicating the lowest self-esteem and 30 the highest.

Scores between 15 and 25 are within normal range; scores below 15 suggest low self-esteem; scores above25 suggest high self-esteem.

Items number 3, 4, 5, 6, 9 were reversed for scoring and became strongly disagree(3), disagree(2), agree(1), and strongly agree(0). Translation into Arabic language was done through Back Translation Procedure.

Reliability of the tool was held on the same 20pioletpost mastectomy women. Test-retest-reliability coefficient was held on the same patients by the same investigator within 14 days interval in the same setting. Its value for 10 items was (r = 0.9).

IV. Developed questionnaire to assess: Quality of Sexual Life among Post Mastectomy Women: (Appendix IV))

This questionnaire was developed by the investigator in Arabic, and English language through Back Translation Procedure to assess the Quality of Sexual life among post mastectomy women.

Post-Mastectomy Quality of Sexual Life Scale(PMQSLS):

This developed questionnaire is to assess quality of sexual life among post mastectomy women. The tool is composed of 20 items.

The process of Designing, and Developing (PMQSLS):

First stage: Conceptual framework (Review of literature):

The designed questionnaire included the following:

Sexual satisfaction which is a broad construct closely linked to overall relationship satisfaction, Sexual satisfaction has been found to be positively correlated with frequency of sexual activity frequency and

consistency of orgasm as well as level of intimacy and partner communication. Numerous studies have found that sexual satisfaction is positively associated with indicators of relationship quality such as love, commitment, and stability, and is inversely related to likelihood of divorce **(Yela, 2000& Sprecher, 2002)**.

Assessment of sexual satisfaction is used as one of the standard indicators of sexual health disturbances. Thus, items measuring overall sexual satisfaction and contentment are often included in composite measures of sexual dysfunction **(Stulhofer, Busko& Brouillard, 2010).**

Sexual satisfaction is often assessed with either one-item (How satisfied you are with your sex life?) or two-item indicators (physical and emotional satisfaction with primary sexual relationship **(Stulhofer, *et. al.*, 2010)**.

Many factors have been discussed as contributing to a woman's sense of sexual satisfaction. These include social factors such as age, marital status, and income level, personality/affective factors such as self-esteem, sexual guilt, selfishness, empathy, irritability, anger and background variables such as physical affection, positive sexual attitudes in the family of origin and sexual education **(Belanger, Laughrea& Lafontaine, 2001).**

Second stage: (The Scale construction):

This scale is developed to measure two dimensions of quality of sexual life i.e. Sexual satisfaction and sexual wellbeing among post mastectomy women. The researcher developed the items of this scale from a Pool of 65 items which selected in accordance with the pervious conceptual framework. These 65items presented in two questionnaire

with the following references **(Cindy Meston& Paul Trapnell,2010and Stulhofer, Busko& Brouillard, 2010).** The first Questionnaire is a brief, 30 items measure of sexual satisfaction and sexual distress, composed of five domains supported by factor analyses: contentment, communication, compatibility, relational concern, and personal concern, The second questionnaire is brief, 35 items, composed of five domains of sexual behavior including sexual sensations, sexual awareness/focus, sexual exchange, emotional closeness and sexual activity. The researcher selected and modified ten items from each questionnaire. To select the most applicable items, three criteria were applied to the 65 items: most important, most culturally appropriate and most useful. Accordingly the total number of the new developed tool amounted to 20 items.

Third stage: (Scoring):

A four point Likert rating scale format was used to score the 20 items, as follows: (1) Strongly dissatisfied, (2) Dissatisfied, (3) Satisfied, (4) Strongly satisfied. Negative scored items are reversed during statistical tabulation. These questions were numbers 2, 3, 4, 5, 6, 7, 8, 9, and 10. The scoring became Strongly dissatisfied (4), Dissatisfied (3), Satisfied(2) and Strongly satisfied (1). The final score of the questioner the sum of the 20 items, ranging from 0 to 80.Women with score ≥ 40 (the optimal cut-off score) have satisfactory quality of sexual life than those with scores ≤ 40.

Fourth stage :(Validation process):

Validation process was used both for face validity, and content validity was done by the judgment of six professors (three psychiatrist, two assistant professor in medical oncology and one professor specialized in psychiatric, and mental health nursing).

This instrument was also reviewed by an expert in medical statistics to validate its scoring system. This panel of experts approved both face, and content validity of this instrument, and its scoring system. No further modifications were suggested. The tool became ready for testing.

Fifth stage:(Instrument Reviewing):

Peers and expertise reviewed the scale for face and content validity and agreed upon it. No further modifications were suggested. The tool became ready for testing.

Sixth stage: (Instrument Testing):

A pilot study was conducted to test the instrument preface validity and reliability. The study was done on20 subjects of the sample, and gained participants acceptance. Reliability of the tool was held on the same 20 post mastectomy patients. Test-retest-reliability coefficient was held on the same patients by the same investigator within 14 days interval in the same setting. Its value for 20 items was (0.8).

II) Operational design

The operational design included face validity and content validity of the tools, and pilot study.

- **Face and content validity of the study tools:**

The validation process of all study tools used both face and content validity by the judgment of a jury of six professors (three psychiatrists, two professors in medical oncology, and one professor specialized in psychiatric and mental health nursing). This panel of experts approved both face, and content validity of the study tools, and its scoring systems. No further modifications were suggested.

- **Pilot Study:**

1) A pilot study was carried out on a total of 10% of the sample (20 of post mastectomy women) according to the criteria of selection at Oncology Center of Mansoura University before starting the data collection to test the clarity and applicability of the tools.
2) Necessary modifications were done as the following:

Socio demographic data: Two items: date of breast cancer diagnosis is removed, education options is classified as illiterate, read and write, elementary, secondary and academic education instead of illiterate, moderate and high education and psychiatric diseases changed into psychiatric complains or distress.

N.B.: The pilot study subjects were excluded from the study sample.

III) Administrative Design

- **Methods:**

1) Official approval for conducting this study was obtained from the director of Oncology Center of Mansoura University and the head of the Medical Out-patient Clinics of Oncology Center of Mansoura University.
2) Once permissions were granted to proceed in this proposed study, 200 post mastectomy women who fulfilled the inclusion criteria were approached by the investigator to gain their approval to participate in the study.
3) The investigator started data collection by introducing himself to participants, explain to them the purpose of the study and assure confidentiality.

4) Then verbal and informed written consent from the patients were obtained.
5) Each patient was individually interviewed to collect the necessary data in privacy.
6) Patients' privacy was maintained, and patients were informed about their rights to withdraw from the study at any time without penalty.
7) The participants who refused to continue filling the questionnaire were excluded from the sample size.
8) The investigator collected data over a period of 5 months from the beginning of May 2014 to the end of September 2014. Structured interviews conducted in Medical outpatient Clinics of Oncology Center of Mansoura University. The interview with each patient lasted for 30 to 45 minutes.
9) All tools of data collection were coded to avoid declaration of any personal information of sample information.

- **Ethical considerations:**

Ethical consideration was obtained from the Research Ethics Committee of the Faculty of Nursing – Mansoura University. Also, an official permission was obtained from the director of the Oncology Center of Mansoura University upon a letter issued from the Faculty of Nursing including the aim of the study, procedure and number of the sample. All participants in the sample and health care providers were informed about the purpose and benefits of the study and were informed that the investigator is a master candidate at the Faculty of Nursing, Mansoura University.

Participants were assured that the study posed no risks or hazards to their health. The investigator emphasized that participation in the study was entirely voluntary and they have the right to withdraw at any time without giving any reason and without any effect on their care or health. Informed consent was obtained from them. Measures were taken to ensure confidentiality through data collection and coding by keeping data in a secure place away from the hospital or university.

Participants were informed that the questionnaire sheets will be coded without names and the collected data will be used only for the purpose of the study.

- **Limitations of the study:**

1) It has been taken a long time (at least one month)to have permission from the director of Oncology Center of Mansoura University and from the head of outpatient clinic of this center.
2) The investigator faced many difficulties in assembling accurate statistics about the number of post mastectomy women attending hormonal therapy follow up at outpatient clinic of Oncology Center of Mansoura University and this leading to spending long time before reaching accurate calculation of the sample size.
3) Some patients fitting the inclusion criteria refused to participate in the study for being ashamed of discussing their sexual life.
4) Overcrowding in the out patients clinic make the investigator face many difficulties in collecting data from patients.
5) Some physicians, nurses and other health care providers of Oncology Center of Mansoura University refused cooperation with the investigator that led to initiation of number of difficulties to reach to the adequate number of the sample as well as taking long time for data collecting.

IV) Statistical design

Data were analyzed with Statistical Package for Social Science (SPSS) version 16. The normality of data was first tested with one-sample Kolmogorov-Smirnov test. Qualitative data were described using number, and percent.

Continuous quantitative variables were presented as M (Mean)± SD (standard deviation) for parametric data, and Median for non-parametric data. The two groups were compared with Student t-test (parametric data), and Mann–Whitney test (non-parametric data). Analysis Of Variance (ANOVA test) used for comparison of means of more than two groups. Pearson correlation used for the correlation between continuous parametric data while Spearman correlation to correlate between continuous non-parametric data.

Level significance:

For all above mentioned statistical tests done, the threshold of significance is fixed at 5% level (p-value). The result was considered:

- Significant when the probability of error is less than 5% ($p < 0.05$).
- Non-significant when the probability of error is more than 5% ($p > 0.05$).
- Highly significant when the probability of error is less than 0.1% ($p < 0.001$).
- The smaller the p-value obtained, the more significant are the results.