Chapter – III

RESEARCH METHODOLOGY

Methodology of research includes the steps, procedures and strategies for gathering and analyzing data in a research investigation. It includes aspects like research approach, samples, sampling technique, development of data collection tools, intervention, pilot study, data collection and plan for data analysis.

The present study was aimed at determining the effectiveness of selected interventions on reduction of holistic symptoms and prognosis of patients with head and neck cancer in a selected hospital, Neyyoor, Kanyakumari District.

RESEARCH APPROACH

As the aim of the present study was to compare the effectiveness of selected interventions on reduction of holistic symptoms and prognosis of patients with head and neck cancer, quantitative research approach was selected.
**RESEARCH DESIGN**

Research design guides the researcher in planning and implementing the study. According to Hott and Budin (2006), it is a blueprint for the conduct of study that maximizes control over factors that could interfere with the study’s desired outcome. The research design adopted for the study was quasi-experimental design. In that Pre-test Post-test control group design was adopted. The schematic representation is given in Fig 2.

**SETTING**

The study was conducted at International Cancer Centre, Neyyoor which is the pioneer institute for cancer treatment in Tamilnadu. It is a wing of the Kanyakumari Medical Mission, Neyyoor. Kanyakumari Medical Mission Hospital, Neyyoor which functions under the Kanyakumari Diocese and it was started in 1838, which has six hundred beds catering services to all types of patients. Among that 150 beds are exclusively for cancer patients. This setting is a central referral hospital for a population of about 5 lakh residents of surrounding rural, urban and semi urban areas. It has all the facilities including linear accelerator, radiation therapy, chemotherapy and surgery.
FIG: 2 RESEARCH DESIGN

Pre-test
Day 1
- Demographic Profile
- Symptoms check list
- Quality of life Assessment
- Pain Assessment
- Sleep and Physiological Parameters Assessment
- Oral Assessment

Intervention
Day 1 - 6
Group I
- Counselling
- Financial support
- Oral care

Group II
- Counselling
- Financial support
- Oral care
- Music therapy

Post-test
Day 1 - 7
Group I
- Symptoms check list
- Quality of life for Assessment
- Pain Assessment
- Sleep and Physiological Parameters Assessment
- Oral Assessment

Group II
- Symptoms check list
- Quality of life Assessment
- Pain Assessment
- Sleep and Physiological Parameters Assessment
- Oral Assessment
POPULATION

Population covers the entire group of subjects under study. According to Ranjit (2008) population refers to the largest body of cases or individual that is being researched, which confirms to the specific set. In this study the accessible population refers to patients with head and neck cancer admitted in the inpatient department of the International Cancer Centre, Neyyoor for treatment during the period of November 2007 to November 2008.
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SAMPLE AND SAMPLING TECHNIQUE

The sample consists of a subject of the units from the defined population. Two hundred patients who fulfilled the inclusion criteria were selected for the study. The patients who were admitted in the hospital first time during the period of study (November 2007 to November 2008) were only included. Two groups were selected for the study. To allot the patients to Group I (100 patients) and Group II (100 patients) random allotment of weeks was followed. Patients admitted in 1st and 3rd week were allotted to Group I and patients admitted in second and fourth week were allotted to Group II. All the available sample during the data collection were selected.

Inclusion criteria

Patients diagnosed as head and neck cancer.

- Undergoing either chemotherapy, radiation therapy, or combination of therapies.
- With stage I and II cancer.
- Minimum of hospital stay for seven days.
- In age group between 30 and 80.
- Able to follow the instructions.
- Willing to listen to music and accept counselling.
Exclusion Criteria

Patients with head and neck cancer who are
- Neurologically affected.
- Terminally ill.
- Not willing to listen music and counselling.
- Under going surgical treatment

ESTIMATION OF SAMPLE SIZE

The sample size is estimated by taking the mean differences and standard deviations of cancer population as follows.

For testing the measures two Groups (Expert control)

- Estimated effect $\gamma (Ela) = 0.30$
- Type I error $\alpha = 0.05$
- Power of test $(1-\beta) = 0.80$
- Approximate sample size = 174

(Ref:- Table 19-6 chapter - 19, page 492. Nursing Research, Principles and methods, VI Edition, Devise F. Polit and Befna Dette P. Hungler). For rounding the sample in hundreds, the total samples selected were 200. By adopting random week assignment, 100 samples were allotted to Group I and 100 samples were allotted to Group II.

Final Sample size

- Control Group (Group I) = 100
- Experimental Group (Group II) = 100
DATA COLLECTION TECHNIQUES AND INSTRUMENTS

The most trustworthy evidence that can be used in evaluating the outcome of research investigation is by developing appropriate instruments to examine the specific variable. Treece and Treece (1986) stated that the instruments selected in a research should be to obtain data for drawing conclusions pertinent to the study.

Development of Tools

Literature search was done to find out the suitability of the existing tools for present study. The investigator could get tools to measure few variables under study and has developed tools to measure other variables after an extensive review of literature, Internet search and discussion with experts. Tools were developed in English for data collection process.

The interviewing was considered to be the most efficient and objective method of deriving necessary information from the clients. This method was followed because direct questioning is appropriate in assessing the demographic data of the patients with head and neck cancer.
The final tool consisted of 6 sections such as

**Section 1** - Socio Demographic and Clinical Data- Prepared by the investigator.

**Section 2** - Symptoms Check List - prepared by the investigator.

**Section 3** - Universal Pain Assessment Scale- Standard tool.

**Section 4** - Sleep and Physiological Parameter Assessment Scale - Prepared by the investigator.

**Section 5** - Modified University of Washington Quality of Life Questionnaire - Standard tool modified by the investigator.

**Section 6** - Radiation Mucositis Scale- Standard tool.

**DESCRIPTION OF THE INSTRUMENTS**

**Section 1 Socio- Demographic and Clinical Data**

Consists of structured questions that assessed the age, sex, marital status, income, education, occupation, residence, type of family, religion, social support, diagnosis, duration of diagnosis, stage of cancer, reason for present admission, previous experience of counselling, and number of previous hospitalization.
Section: 2 Symptoms Check List

Symptoms check list was in the form of checklist and had a total of 20 items. Symptoms were grouped under physiological, psychological, and spiritual. Physiological symptoms consisted of restlessness, difficult to swallow, loss of sleep, loss of speech, disfigurement, difficulty in chewing, palpitation, fatigue, oral mucositis, loss of appetite, loss of weight, and loss of hair. Psychological symptom consisted of impaired concentration, irritability, anxiety, forgetfulness, and worry. Spiritual symptom consisted of spiritual distress.

Section: 3 Universal Pain Assessment

Universal pain assessment scale is a standardized one. It is scored in three levels as mild pain, moderate pain and severe pain. The score of 1-2, was considered as mild pain, 3-6 was considered moderate pain and 7-10 was considered as severe pain.

Section: 4 Sleep and Physiological Parameter Assessment Tool

This tool was developed by the investigator. This section assessed the blood pressure, pulse rate before and after music therapy, duration of sleep, and subjective evaluation of sleep by the patient.
Section : 5  Modified University of Washington Quality of life Questionnaire

The modified University of Washington Quality of life Questionnaire was modified by the investigator.

This section consisted of twenty divisions. They are pain, appearance, activity, recreation, swallowing, chewing, speech, shoulder, taste, saliva, mood, anxiety, sleep, finance, social support, spiritual, counselling, and three general questions. Each division has 5 options scored 0-4. It was assessed before the treatment on the day one and after the treatment on day seven. One division had reverse scoring. All experts suggested to have scoring like other divisions. So it was changed as per the suggestion of the experts.

Section : 6  Radiation Mucositis scale

Radiation mucositis scale is a standardized scale. It had 5 options, they were no mucositis – 0, white discoloration – 1, erythema – 2, pseudomembranes – 3 and ulceration – 4. It was assessed on day one and on day seven. The scale consists of high score of 4 and low score of 0 considering the intensity of the ulcer.

CONTENT VALIDITY

The content validity of the tool was established by giving to eleven experts. Experts group consisted of four experts from oncology
and medical departments, five experts from the field of nursing and two experts from the field of music. The minor corrections and suggestions given by the experts were incorporated in the tool after discussion with the research guide.

**Pre-testing**

The tools were pre-tested on twenty patients with head and neck cancer by administering it to those admitted in International Cancer Centre, Neyyoor. The average time taken for assessment was 25–30 mts. There was no difficulty found in doing the assessment.

**DESCRIPTION OF THE INTERVENTION**

The interventions used in the study were music therapy, counselling, oral care, and financial support.

**Music therapy**

*Description*

- Experts accepted standardized flute, piano and veena instrumental cassettes were used.
- Head phone was given for each patient in Group II to listen music for half an hour from 8.30 to 9.00 p.m. after finishing their routine care.
- Before administering the music therapy, blood pressure was checked.
- Before and after pulse rate was checked.
The next day morning, duration of sleep, and blood pressure were assessed.

Music therapy was given for seven days continuously everyday night half an hour after the routine care.

Counselling

Counselling was given for patients in both groups. It was given by the researcher on day 1 and day 7. On selection of the study subject, a brief introduction about the self was given to the subjects followed by detailed explanations regarding the purpose of the study and expectation from the patients with head and neck cancer during the data collection was done.

- Created a calm and quiet environment.
- Time was given for relaxation.
- Patients were allowed to express their feelings and difficulties.
- Investigator identified their problem from the discussion.
- Counselling was given based on their need and problems.
- It took 40-45mts on the day one because most of the patients cried and expressed.

Counselling for patients undergoing Chemotherapy

- Counselling was given on side-effects and management.
- Psychological support was given.
- Benefits of chemotherapy were explained.
Counselling for patients undergoing Radiation therapy

Counselling was given on

- side-effects of radiation therapy.
- diet
- how to take care of radiation mucositis

Counselling on Seventh day

On day 7 for counselling it took 30mts for each patients

- They themselves came forward to ventilate their feelings.
- They asked many questions for clarification.
- Based on their doubts counselling was given.
- The counselling session was terminated by the investigator by giving positive feedback to the patients.

Financial Support

Both the groups were supported by religious financial support group called as Pallathakin Leeli.

- Income was assessed during the data collection as well as during the counselling.
- Based on their financial viability, the patients were referred to the support group for the financial support.
- They received food for 3 times/day.
- Financial assistance for chemotherapy, radiation therapy was given with free bed.
Oral Care

- Oral care was given every Q2H for patients in both groups.
- Tantum solution was used for oral care, which comes in 100ml bottle.
- Five ml of the solution was added to the 100ml of boiled cooled water (1:20 or 5%).
- The mouth care was given with prepared Tantum solution Q2H.
- First two to three times the investigator assisted the patients to do it and then it was taught to the patients as well as the relatives.
- Every day it was observed by the investigator to ensure that the patients do it.
- Oral cavity was assessed on the day 1 and 7.
- Advised to take mouth wash Q2H when the patient was awake.

Pilot Study

A pilot study was conducted during October, 2007 to assess the feasibility of the study and also to determine any major flaw in the design used. It also helped to determine the plan of statistical analysis. Prior to the study, administrative permission was obtained from Medical Superintendent and Head of the Department of International
Cancer Centre, Kanyakumari Medical Mission, Neyyoor. Twenty patients with head and neck cancer were selected as sample after random assigning of week and those who fulfilled the inclusion criteria. Patients were assessed for seven days.

Reliability of the tool

The reliability of the observation check list was established using inter rater reliability on 20 patients. The coefficient correlation was computed and it was 0.99. The tool was found reliable. Other tool reliability was established using test-retest method and it was found reliable.

Ethical consideration

The following ethical factors were considered during the period of study.

1. The study was approved by the research committee.
2. The content validity of the tool was obtained with the concurrence of all the experts and the guide.
3. Formal written permission was obtained from the Medical Superintendent of the Kanyakumari Medial Mission, Neyyoor to conduct the study.
4. Ethical committee approval was obtained from International Cancer Centre, Neyyoor.
5. Informed consent from the respondents was taken on the selection of the subject.

6. Full confidentiality was maintained throughout the conduct of the study.

PROCEDURE FOR THE DATA COLLECTION

The data collection was done alternative weeks for both groups. The patients were selected based on the inclusion criteria. A brief introduction about the self was given to the subjects following detailed explanations regarding the purpose of study. Obtained written consent from the participants. All assessments were done before starting the interventions on the first day. Counselling was given on the day one and day seven. It took around 40-45 mts. The procedure was explained to the patients. Oral care was given Q2H when the patient was awake. Financial assistance was provided for all patients.

Patients were assessed according to the plan of assessment and interventions (Fig. 3).
FIG. 3: THE ASSESSMENTS DONE AND INTERVENTIONS GIVEN TO BOTH GROUPS

Day

Group I

- Demographic profile
- Symptoms check list
- Quality of life assessment
- Pain assessment
- Sleep assessment
- Oral assessment

Group II

- Demographic profile
- Symptoms check list
- Quality of life assessment
- Pain assessment
- Sleep assessment
- Oral assessment

Day 1

Intervention
Day 1 to 7

Group I

- Counselling (Day 1 and 7)
- Financial support
- Oral care

Group II

- Counselling (Day 1 and 7)
- Financial support
- Oral care
- *Music therapy*

Day 1 to 7

Group I

- Pain assessment
- Sleep assessment

Group II

- Pain assessment
- Sleep assessment

Day 7

Group I

- Symptoms check list
- Quality of life assessment
- Pain assessment
- Sleep assessment
- Oral assessment

Group II

- Symptoms check list
- Quality of life assessment
- Pain assessment
- Sleep assessment
- Oral assessment
Data collection for Group I, and Group II was done in alternate weeks. Random week assignment was followed. Patients in Group II received Music therapy for half an hour everyday night after finishing all routine care before the patients go to sleep in addition to intervention done to Group I.

Plan for Data Analysis

The data analysis planned to include both descriptive and inferential statistics.

1. Analysis of subjects socio demographic and clinical profile in the form of frequency and percentage distribution.

2. Frequency and mean distribution used for analyzing symptoms check list.

3. Analysis of variance and ‘t’ test were used to find the association of music therapy, pain and sleep.

4. Two way ANOVA with measures repeated variables