Methods of Investigation
CHAPTER 5

METHODS OF INVESTIGATION

5.1 AIM AND OBJECTIVES

The purpose of the study is to determine the therapeutic effectiveness of Indian music on cancer related pain and its functional symptoms and QOL

To develop guidelines on musical selections in Indian context and approaches that could be adopted for clinical use of MT for future research and practice.

To provide a base for further research with HNC patients with respect to receptivity and adherence to MT interventions.

To conceptualise a complementary treatment approach to cancer pain through music by addressing its functional symptoms.

And to explore recurrent themes that further occur during the course of the study on MT intervention.

5.2 RESEARCH QUESTIONS

The Research questions were 1) if music can be a stimulus of active focus and be a distraction from pain? 2) will preferred music influence reduced perception of pain? 3) can music facilitate a relaxation response and alleviate insomnia and fatigue to alter the perception of pain? 4) can music
relieve feelings of situational anxiety and reduce pain perception? 5) will patients having no knowledge of classical music be benefited by music therapy in relation to cancer pain? 6) will classical Music have a better impact on cancer pain than the preferred music by the patients? 7) will music have a positive effect on the overall Quality of Life of cancer patients in reducing the pain perception? 8) will music reduce the analgesic requirements of cancer patients in pain?

5.3 SAMPLE AND SETTING

Samples were chosen from Cancer Institute (WIA), Chennai, India, a Regional Cancer Center for cancer research and treatment in the Ministry of Health of Family Welfare of the Govt. of India. The Institute was chosen because a large number of cancer patients seek treatment from different parts of India in view of the excellent facilities available in the Institute for treatment.

45 in house patients admitted in the general wards for treatment from a low socio economic strata were drawn following the inclusion and exclusion criteria and were randomly assigned to one of the three conditions (experimental preferred music intervention, experimental Karnatic music intervention or a control group.

5.3.1 Sample size

1. The sample size was determined keeping in view the following issues that were to be addressed.
2. The rigorous inclusion and exclusion criteria to control the site of the disease, stage of the disease, the treatment regimen and pain issues relating to the disease

3. The need to control the socio economic strata, the music training levels, listening pattern and the language spoken by the subjects to have a homogenous sample

4. The need for taking complete consent from the subjects considering the advanced stage of the disease

5. The need for taking account the physical condition of the subjects to participate in the MT intervention and record the responses through the psychometric tools to meet the rigorous needs of a scientific inquiry.

6. The time taken for each MT intervention for the subjects patient and the long duration of one month of the intervention for each patient to match the time limit of the study.

7. Availability of the sample meeting all the above issues in a single center.

5.3.2 Eligibility Criteria

The criteria for participation in the study included

(1) Oral cancer patients of

a) Carcinoma Buccal mucosa (Cancer of the inner lining of the cheeks)
b) Carcinoma Tongue (Cancer that begins in the tongue)

c) Carcinoma – Palate (Cancer at the roof of the mouth. The front portion is hard palate and the back portion is soft palate)

d) Carcinoma - Labial mucosa (Cancer of the inner lining of the lips)

e) Carcinoma – Alveolus (Cancer of Alveolus)

f) Carcinoma Gingivum (Cancer of the gums)

in advanced stages III and IV classified under the TNM staging system (A system for describing the extent of cancer in a patient’s body. T describes the size of the tumor and whether it has invaded nearby tissue, N describes any lymph nodes that are involved, and M describes metastasis which is spread of cancer from one body part to another)

2) receiving in house radiation treatment

3) having documented cancer related pain and receiving scheduled analgesics (A drug that reduces pain)

4) having an ability to speak and understand Tamil

5) with no hearing dysfunction

6) in the same socio economic strata.

5.3.3 Exclusion criteria

The exclusion criteria were 1) Patients having musical background 2) who are trained in music 3) who have hearing problems and 4) who were taking treatment for psychiatric problems were excluded from the study.
5.4 HYPOTHESES

Based on the review of literature made for the study, the specific research hypotheses that were formulated were

1) Music will be an active focus of attention and be a distraction from cancer related pain.

2) There will be a significant reduction in levels of pain experienced by the subjects by the experimental group receiving preferred music as intervention than the control group receiving no MT intervention.

3) There will be a significant reduction in the levels of situational anxiety between the experimental groups and the control group after MT intervention

4. There will be significant improvement in sleep quality between the experimental group and the control group after MT intervention.

5. There will be a significant reduction in levels of fatigue experienced by the patients between the experimental groups and the control group after MT intervention.

6. There will be a significant improvement in QOL between the experimental group and the control group after MT intervention

7. There will be a significant decrease in the quantum of analgesics used in the music intervention group than the control group.

8. Music will elicit relaxation responses and will help onset of sleep
5.4.1 Null Hypotheses

1. There will not be a significant improvement due to MT intervention between the experimental groups and control group in sleep quality.

2. There will not be significant difference due to MT intervention between the quantity of analgesics used by the subjects between experimental groups and control group.

As the study wanted to assess the feasibility of the therapeutic implications of music, themes relating to how many patients were interested in taking up the intervention, how many were able to complete the intervention, the receptivity for the MT sessions, the problems encountered by the disease and the treatment which interfered with taking up the treatment, the adherence to complete the intervention were also documented.

5.5 METHOD

Due to the preliminary nature of the investigation by the researcher, triangulation quantitative/qualitative methodology was resorted to. Formative studies with focus group design, survey, case study design, interviews and qualitative tools developed by the researcher to record the effectiveness of music on cancer pain and its functional symptoms, psychological responses check list to document the recurrent themes that emerged while listening to music and end of the intervention self report recorded by the patients were used along with the quantitative method. The
quantitative method used a pre and post test experimental and control design, which was subjected to statistical analysis. There is a lack of specific and well evaluated instruments of measurement required for research and documentation in music therapy. (Moreau, D.V. 2003). However, most of the cross-cultural quantitative studies use standardised tools to document the observations and the effects of MT as there is a need to apply music therapy scientifically.

5.6 ETHICAL PRECAUTIONS

Informed complete consent was obtained from the patients for participation in the study. The patients were instructed to respond to only what they were comfortable with to avoid inappropriate burdening of the advanced stage cancer patients. The patients were informed of the freedom to get dropped out of the intervention whenever they wanted.

5.7 INTERVENTION

The independent variable (The variable in an experiment that is manipulated or compared), the therapeutic use of music was assigned to the first experimental group in the form of preferred type of music selected through formative studies based on focus group discussions and survey (light devotional music). The second experimental group received Karnatic music for therapeutic administration. The duration of the intervention was for 30 minutes through a portable CD player with lightweight stereo headphones. Informed consent was obtained from all the participants and the intervention
was carried out in a separate room on a comfortable couch in a lying relaxed position.

5.8 STATISTICAL ANALYSIS

Descriptive statistics for demographic variables, Independent sampling t test between experimental groups and control group, paired sample t test between pre and post test groups Pearson Correlations, Analysis of Variance (ANOVA) and multiple stepwise linear regression analysis were used to analyse the data collected.

5.8.1 Assessments and Instruments

The Brief Pain inventory (BPI) Cleeland, C.S. (1989) was to assess the severity of pain and the impact of pain on daily function. The instrument has been documented as a reliable and valid instrument with cronbach alpha reliability ranging from .77 to .91 and validated in about 24 languages by examining consistency of its two-factor structure (See annexure 2: 2.1 page-32).

The World Health Organization adopted the BPI to evaluate the effectiveness of national cancer pain relief programs. The intensity subscale of the BPI consists of four items that ask patients to rate their pain intensity as worst pain, least pain, and average pain in the past week, as well as pain now. Each item is rated on a scale from 0 (no pain) to 10 (the worst pain imaginable). Beck (2005).
The operational definition of the variable: For independent sampling tests, subjective reports of worst pain, least pain, average pain, ‘pain now’, general activity, mood, walking ability, normal work, sleep, relations with people and enjoyment of life were taken for analysis.

For Pearson correlation and regression analysis, all the pains (worst, least, average and pain now) were taken into account.

Pittsburgh Sleep Quality Index (PSQI) by Buysse et al. (1989), a self report questionnaire was used to measure sleep quality and patterns of sleep. It differentiates “poor” from “good” sleep by measuring seven areas: Subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbance, use of sleep medications and day time dysfunctions over the last month and 6 weeks. The client self-rates each of these seven areas of sleep. A sleep disturbance score is computed by taking the sum of 10 items that assess the degree to which a variety of factors have interfered with sleep. Scoring of answers is based on a 0 to 3 scale, whereby 3 reflects the negative extreme on the Likert Scale. A global sum of “5” or greater indicates a “poor” sleeper. Smyth (1999). The PSQI has reliability and validity when used in older adults Buysse et al. (1991). It is a valid and reliable instrument to use in oncology populations and has internal consistency and a reliability coefficient (Cronbach’s alpha) of 0.83 for its seven components. (See annexure 2: 2.3 page-40)

Operational Definition of the variable: The sum of the scores of all the questions were taken for statistical analysis.
Spielberger State Trait Anxiety Inventory (STAI - s): was used to measure state anxiety. Anxiety was assessed at the base line with the STAI Spielberger (1999). The STAI was completed immediately after the diagnosis, during MT and radiation therapy intervention and after radiation and MT interventions. The STAI state portion measures feelings of apprehension, tension, nervousness and worry. Scores increase in response to physical danger and psychological stress. The scale consists of 20 statements that evaluate how the patients feel "right now" with scores ranging from 20 to 80 rated on a 1 (not at all to) 4 (very much). The scale has been documented to be reliable and valid and had been extensively used with cancer patients and music therapy studies. (See annexure 2: 2.2 page-38).

Operational Definition of the variable: Composite scores of all the questions from 1 to 20 of the State portion as per the scoring pattern.

Schwartz Cancer Fatigue Scale (SCFS – 6) by Schwartz, A.L. (1997) assessed cancer related fatigue (CRF), a six item short questionnaire measures patient perceptions of the preceding 2-3 days by a 5-point Likert scale on physical and perceptual dimensions. The length of this instrument is an attractive feature for screening and outcome assessments. This tool has shown acceptable psychometric validity under experimental conditions and has been tested for internal reliability. (See annexure 2: 2.4 page-13).

Operational definition of the variable: Composite scores of all the six questions were taken for analysis
Quality of life Questionnaire (Version 1) by Vidubala, E (2005) assessed the QOL in the domains psychological well being, self-adequacy, physical well being, confidence in self-ability, external support, pain, mobility, optimism and belief, interpersonal relationship and self-sufficiency and independence. The questionnaire has 38 items and was developed to suit the Indian context and population. The tool is found to be highly reliable, the internal consistency using Cronbach alpha test was 0.90 and split-half reliability was 0.74. (See annexure 2: 2.5 page-4).

Operational Definition of the variable: The global scores for the questions from 1 to 38 are used for statistical analysis to assess the change in QOL.

5.8.2 Translation of the Questionnaires and Inventories

It became necessary to translate all the tools selected for the study to be translated into Tamil as the subjects chosen were all non English speaking people whose literary levels were low and could not comprehend the language. The questionnaires and inventories were duly translated into Tamil, back translated in to English and was certified by a competent authority for its correctness.

5.8.4 Bias in Assessment

The investigator’s bias was eliminated by recording the daily assessment and the responses of the patients, before and after the musical session and the respondent’s bias in giving socially desirable responses was
tested by assessment by an independent observer by assessing the patients before and after the music sessions on a random basis.

The independent observer who was a psychologist at Cancer Institute, Adyar and a research scholar with University of Madras was apprised of the nature of the study, the aim and objectives and the methodology and also was briefed of the assessments that are to be made with the patients.

5.8.5 Inter-rater Reliability

The inter-rater reliability between the assessments by the researcher and the independent observer was tested to eliminate bias. The cuppa value for the inter-rater reliability was 0.90.

5.8.6 Qualitative Assessments

A psychological responses sheet checklist was developed to document the experiences of the patients and their moods to explore the possible positive effects of listening to music.

Other qualitative assessments made were observational behaviour data for each session, end of study self report data, a log book to mark the adherence to the treatment, reasons for not attending the sessions and schedule of pain medications.
5.9 PROCEDURE

The procedure for the intervention for all the participants was standardised. When the patients completed their investigations for diagnosis and treatment and admitted in the hospital for radiation treatment, the researcher invited them to participate in the study after explaining the potential benefits of the therapeutic usefulness of music. After providing consent, the participants completed base line measures of pain, fatigue, anxiety (state), sleep quality and QOL with the help of the researcher helping them with the questions on the first day. On the consequent day, they were assigned randomly to one of the three intervention groups and were given the CD walkman and the head phones. The patients completed the bi weekly assessment of pain and the functional symptoms of pain schedule developed during the study to know the levels of pain and the other symptoms at that particular point of time, taking into consideration, the analgesic effects of the pain medication they received. The patients were made to lie down comfortably in the bed and light devotional songs to the preferred music group and Karnatic music to the classical music group were administered for 30 minutes. The levels of volume were adjusted for the patients by the researcher and the patients listened to the music. When the patients completed listening to the music for 30 minutes, the bi weekly assessment schedule of pain and its functional symptoms was administered to assess the effect of music during and after listening to the music. The patient also filled in the psychological responses checklist to record his experience during the intervention All the responses were recorded by the researcher verbatim in a
tape recorder to eliminate bias in noting down the responses. After 15 days and at the end of 30 days, the objective assessments using the standardised tools were made again and a diary maintained by the researcher for the end of intervention interview reported by each patient after MT intervention is over. The researcher also on all the days of intervention, filled up the adherence schedule and the analgesics schedule.