CHAPTER III

RESEARCH METHODOLOGY
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This chapter deals with the methodology implemented to determine the effectiveness of Comprehensive Nursing Intervention Programme (CNIP) on anxiety, fatigue, self-efficacy and QOL among patients undergoing CABG surgery in a tertiary care hospital. It includes research design, research setting, population, sample, randomization, sample size, sample selection criteria, administration, scoring procedure and its interpretation, pretesting, validity and reliability of the research instruments, pilot study, data collection procedure and statistical analysis used.

Research Approach

The present trial aimed to determine the effectiveness of Comprehensive Nursing Intervention Programme (CNIP) on anxiety, fatigue, self-efficacy and QOL among patients undergoing CABG surgery. Hence, a quantitative research approach was adopted to achieve the objectives of the study.

Research Design

The randomized controlled trial (RCT) was adopted as research design for the present study. RCT is the most rigorous method of evaluating the effectiveness of healthcare interventions between the experimental and control group. In randomized controlled trial, the participants are randomly assigned to the experimental (intervention) group or the control group (Kabisch, Ruckes, Grafe, & Blettner, 2011).
The schematic presentation of the study design is developed according to the CONSORT (Consolidated Standards of Reporting Clinical Trials) statement 2010 (Moher et al., 2010) and presented in figure 7. The present study design has all the properties of RCT and it follows the guidelines of CONSORT and is registered in the Clinical Trial Registry of India (CTRI) with the number CTRI/2015/09/006173 (Appendix-A9).

The samples (patients undergoing CABG surgery) were selected from the same setting and randomly allocated into experimental and control group using computer generated block randomization and the experimental group received comprehensive nursing intervention programme whereas the subjects in the control group received routine care in the hospital.

**Research Setting**

The setting for the study was department of cardiovascular and thoracic surgery, Kasturba Hospital, Manipal, a tertiary care hospital. The hospital renders outpatient, inpatient, emergency and diagnostic services in almost all medical, allied health and indigenous fields. The bed strength of the hospital is 2032 with 80% patient occupancy rate and adequate staffing.

Department of cardiovascular and thoracic surgery comprised of outpatient department (OPD), SM2 ward, CTI ward and C ward. The average number of CABG surgeries done in this hospital is 12 - 15 per month. The patients gets admitted two or three days prior to CABG surgery in CTI or SM2 ward and spend 2 -3 days in the C ward (immediate postoperative intensive care unit) after CABG surgery, then patients are shifted
to stepdown ICU (CTI Ward). Patients are usually discharged from CTI ward one week after the surgery and visits the surgeon for the follow up in the OPD.

**Population**

The patients in the age group of 35 - 70 years subjected to CABG surgery at Kasturba Hospital, Manipal, Udupi, Karnataka were the population for the study.

**Sample**

The samples for this study were patients who underwent CABG surgery and who fulfilled the inclusion and exclusion criteria.

**Randomization**

Randomization is a process in which patients are allocated to control and intervention group by giving each participant equal opportunity of being assigned to either intervention or control group. The balance between the numbers of subjects in each group is assured during the randomization by adopting block randomization (Stanley, 2007). The random blocks were generated through computer, for 130 samples with the help of biostatistician. Thirteen blocks were prepared each containing 10 numbers (1 meant for experimental whereas 2 for control group). The thirteen blocks were individually put in sealed, sequentially numbered small opaque envelopes and altogether they were put in another big envelope and kept with the safe custody of research investigator.

As and when the patients were getting admitted for CABG surgery, after assessing the eligibility criteria, the details about the study was explained to the patients and they were given with the sequentially numbered sealed opaque envelope, with the instruction to
open the envelope, read the number and if the read number was one, the patient was allocated to the experimental group and number two to the control group. The patient was given the code number based on the randomization. When all the ten numbers in the first envelope were allocated, second envelope was given for the new patient. Following the allocation to the group, the procedure was very well explained to all the patients completely what is expected from them during the study and written consent was obtained.

**Study Variables**

The variables included in the present study are mentioned below

**Independent Variable**

Comprehensive Nursing Intervention Programme (CNIP)

**Dependent Variables**

- Anxiety, Pain, Fatigue, Self-efficacy and Quality of Life
Figure 7. CONSORT (2010) Flow Diagram on Process of Randomized Controlled Trial

Note: ITT = Intention to treat analysis
Sample Size

The sample size of the study was calculated considering quality of life as the primary outcome variable and it was also the highest estimated sample size comparing to other outcome variables. The following formula was used for calculating the sample size (Diggle, Heagerty, Liang, & Zeger, 2002).

\[
    n = \frac{2[Z_{1-\alpha/2} + Z_{1-\beta}]^2 \sigma^2 [1 + (m - 1)\rho]}{m(d)^2}
\]

\[
    Z_{1-\alpha/2} - 1.96 \text{ for } \alpha = 5\% \quad Z_{1-\beta} = 1.28, 90\% \text{ power, } \rho = 0.3, d=3
\]

\(\sigma^2\) - Standard deviation, \(d\) - clinically significant difference, \(m\) - number of measures, \(\rho\) - intra class correlation of repeated measures.

Based on the above formula estimated sample size was 55 in each group, considering the 20% attrition rate in the pilot study 65 was included. Thus, total sample size was 130, 65 in the experimental group and 65 in the control group.

Sampling Criteria

The following criteria were set for the selection of the sample

Inclusion Criteria

- Patients underwent isolated CABG for the first time
- Patients who were subjected to elective CABG
- Patients in age group of 35 -70 years in both gender
- Patients who were weaned off from ventilator within 48 hours
- Patients who can speak, understand, read, write and English or Kannada
- Patients who are willing to participate
Exclusion Criteria

- Patients who could not follow the instructions
- Patients who had cardiac arrest in post-operative period
- Patient who would be taken for re-exploration procedure
- Patients with redo CABG

Data Collection Tools

The following data collection tools were used in this study

1. Socio-Demographic and Clinical Variables
2. Bio-Physiological Parameters
3. Visual Analogue Scale (VAS) - Pain
4. Fatigue Visual Numeric (FVN) Scale
5. State -Trait Anxiety Inventory (STAI)
6. Identity Consequences Fatigue Scale (ICFS)
7. Barnason Efficacy Expectation Scale (BEES)
8. Quality of Life Index (QLI) - Cardiac Version IV

Tool 1. Socio-Demographic and Clinical Variables

This was developed by the researcher and validated by the experts. Part A consisted of socio-demographic information and Part B consisted of information on clinical variables of the samples (Appendix D1).

Part A: Socio-Demographic Variables

It had fifteen items such as age of the patients, gender, religion, educational qualification, occupation, marital status, monthly family income, physical activity, place of
residence, and habit of smoking, habit of alcohol, habit of tobacco, dietary pattern, habit of
regular exercise, and family history. These items did not have any scoring as they were
meant to collect the factual information from the sample.

Part B: Clinical variables

It had nine items such as ejection fraction rate, body mass index, history of
hypertension, diabetes mellitus, heart attack, percutaneous coronary intervention, previous
history of heart surgery, type of CABG and number of ICU stays (in days). These items
did not have any scoring as they were meant to collect the factual information from the
sample.

Validity

To ensure the content validity, socio-demographic & clinical variables proforma
along with research statement, objectives and validation checklist (Appendix C4) were
given to twelve experts (both national and international) from the field of nursing,
cardiovascular nursing, cardiology and cardio vascular and thoracic surgery (Appendix
C1). The experts were requested to give their valuable opinion and suggestions based on
the relevance, accuracy and appropriateness. Initial tool consisted of 17 items for both
socio-demographic and clinical variables. After the content validity, based on the
suggestions from the experts seven items were added (physical activity, use of tobacco,
ejection fraction rate, number of ICU stays, history of previous heart surgery, heart attack,
and percutaneous coronary intervention) and finalized with 24 items (Appendix D1).

Content validity index (CVI) was calculated based on the expert’s opinion.
Calculated I - CVI and S - CVI score for the socio-demographic variables was 0.93 and
0.92 respectively. For the clinical variables I-CVI and S-CVI score for the clinical variables were 0.91 and 0.90 respectively.

**Tool 2. Bio-Physiological Parameters**

It consisted of bio-physiological measures such as pulse rate, respiration rate, blood pressure (systolic and diastolic) and oxygen saturation (Appendix D2). Bio-physiological parameters were measured on 2\(^{nd}\) and 5\(^{th}\) post-operative days in both the experimental and control group.

**Validity**

Content validity was established with opinion and suggestions from 12 experts (Appendix C1). Calculated I-CVI score for the bio-physiological parameters was 0.91.

**Tool 3. Visual Analogue Scale (VAS)**

The visual analogue scale (VAS) is a common tool to assess the pain intensity. The tool was self-completed by the participants (Appendix D3) and the scale is free to use. The participants were requested to mark a circle on the visual analogue scale line at the position that denoted their pain level. Score range of the VAS was from 0 (no pain) to 100 (severe pain) and higher the scores denotes higher the pain level. Pain was measured on 2\(^{nd}\) and 5\(^{th}\) post-operative days in both the experimental and control group.

**Validity**

This is a standardized scale and it is commonly used to measure the pain in various patients and research settings. Numerous studies have utilized this tool to measure pain intensity among the patients who had CABG surgery (Gorji, Nesami, Ayyasi, Ghafari, & Yazdani, 2014).
Pretesting

Pretesting was done by administering the visual analogue scale to five patients after the CABG surgery. The tool was found to be feasible and no difficulty faced by the patients to respond the pain intensity.

Reliability

The stability of the tool was measured by test-retest reliability method by administering to twenty samples. Reliability coefficient was calculated using Pearson’s correlation and estimated r value was .93 found to be good to assess the pain intensity. A previous article reported the test retest reliability of visual analogue scale - pain has shown to be 0.90 (Hawker, Mian, & French, 2011).

Tool 4. Fatigue Visual Numeric (FVN) Scale

The FVN was originally developed by Stanford Patient Education Research Center to measure self-reported fatigue in adults (Appendix D4) and the scale is free to use (Merritta, Cherian, Macaden, & John, 2010).

The participants were requested to mark a circle on the fatigue visual numeric scale at the position that denoted their current fatigue level. The range of score was between 0 and 10, higher the score indicates higher level of fatigue. This tool was administered to measure the immediate postoperative fatigue on 2\textsuperscript{nd} and 5\textsuperscript{th} post-operative period in the patients who underwent CABG surgery in both the experimental and control group.
Validity

This is a standardized scale and it is found to be the appropriate tool to measure the immediate post-operative fatigue (Merritta, Cherian, Macaden, & John, 2010).

Pretesting

Pretesting was done by administering the fatigue numeric visual to five patients after the CABG surgery. The tool was found to be feasible and no difficulty was faced by the patients to report their fatigue level.

Reliability

The stability of the tool was measured by test-retest reliability method by administering to twenty samples. Reliability coefficient was calculated using Pearson’s correlation and estimated r value was .90 found to be reliable to measure the immediate post-operative fatigue.

Tool 5. State Trait Anxiety Inventory (STAI)

The STAI is a standardized instrument for measuring the level of anxiety (Appendix D5) and it was developed and validated by Charles D Spielberger (Julian, 2011). Tool was purchased from Mind Garden, United States of America to use it in the study (Appendix A5). It comprised of two separate self-reports for measuring the state anxiety comprised of twenty items and trait anxiety consisted of twenty items.

In responding to the state-anxiety, the study participants reported how they felt ‘right now’ by rating the intensity of their anxiety feelings on a four-point Likert scale: where 4 = very much so; 3 = moderately so; 2 = somewhat; and 1 = not at all. For
obtaining total state anxiety scores, direct scoring was given for the following items: 3, 4, 6, 7, 9, 12, 13, 14, 17 and 18. For the remaining items scoring was reversed: 1, 2, 5, 8, 10, 11, 15, 16, 19 and 20.

For the trait anxiety, the patients reported how they ‘generally’ feel by rating themselves on a Likert four-point scale where 1 = *almost never*; 2 = *sometimes*; 3 = *often*; 4 = *almost always*. For obtaining total trait anxiety scores, direct scoring was given for the following items: 22, 24, 25, 28, 29, 31, 32, 35, 37, 38 and 40. For rest of the items scoring was reversed: 21, 23, 26, 27, 30, 33, 34, 36 and 39.

The patients’ responses were summed for a total score between 20 and 80, with the higher scores demonstrating the higher anxiety levels. Total anxiety scores can also be classified into the following categories: 60 - 80 (*high anxiety*); 40 - 59 (*medium anxiety*), and 20 - 39 (*low anxiety*) (Koivula et al., 2002).

During the baseline assessment both state anxiety inventory and trait anxiety inventory was administered before the surgery. After the surgery, state anxiety inventory was used on 2nd and 5th post-operative days and during the first month follow up.

**Validity**

This is a standardized scale and STAI is the leading research instrument to assess the level of anxiety worldwide (Nigussie, Belachew, & Wolancho, 2014). The translated version (Kannada) of the tool was utilized for this study. Language validity was established with the help of language experts by following translation and back translation method.
Pretesting

Pretesting was done by administering the STAI to five patients who were following CABG surgery. The tool was found to be feasible and no difficulty was faced by the patients in filling the forms. The average time taken for the patients to fill this instrument was five minutes for each form.

Reliability

Internal consistency of the scale was calculated using Cronbach’s alpha coefficient by administering the STAI to twenty samples. The calculated values for the scale were .82 and .79 for the state and trait anxiety respectively. Hence, it was considered to have adequate internal consistency and reliable to measure the anxiety.

Tool 6. Identity Consequences Fatigue Scale (ICFS)

Identity-Consequence Fatigue Scale (ICFS) was used to measure the comprehensive post-operative fatigue in this study (Appendix D6) and this scale can be used to assess the fatigue in patients following major surgery (Paddison, Booth, Hill, & Cameron, 2006). The investigator got the permission from the author to use this instrument in this study (Appendix A6). ICFS questionnaire consists of 31 items. The first 20 items assess the feelings of fatigue, vigor, impact on concentration and energy and the remaining 11 items are for assessment of impact of daily activities (IDA).

This tool was administered to measure the comprehensive postoperative fatigue during the first month and third month follow up among patients who underwent CABG surgery in both the experimental and control group. The participants reported how they had been feeling for the first eighteen items on a six point Likert scale where: 5 = all of the
time; 4 = very often; 3 = fairly often; 2 = some of the time; 1 = almost never; 0 = not at all,
and for the 19th and 20th items they reported on five point Likert scale where: 4 = I strongly
disagree; 3 = I disagree; 2 = neutral; 1 = I agree; 0 = I strongly agree.

The participants were asked to report how fatigue interfered with their daily
activities for the questions 21 to 31 on five point Likert scale where: 4 = as often as usual;
3 = nearly as often as usual; 2 = sometimes but less than usual; 1 = only occasionally; 0 =
not at all. For obtaining the total fatigue scores, direct scoring was given for the following
items: 1, 2, 4, 6, 8, 10, 12, 13, 15, 16, 17, and 18. For the remaining items scoring was
reversed; 3, 5, 7, 9, 11, 14, 19, 20, and 21-31.

Feelings of fatigue is calculated with the maximum score of 25 based on 5 items,
question numbers 1, 4, 6, 10 and 12. Feelings of vigor is calculated with the maximum
score of 20 based on 4 items, question numbers 3, 5, 7 and 14. Impact on concentration is
calculated with maximum score of 25 based on 5 items, questions number 9, 15, 16, 17,
and 18. Impact on energy is calculated with the maximum score of 28 based on 6 items,
questions number 2, 8, 11, 13, 19, and 20. Impact on daily activities is calculated with the
maximum score of 44 based on 11 items questions number 21 - 31. A total ICFS score is
obtained by calculating the mean of the above 5 subscales. Higher the scores indicates
higher level of fatigue.

Validity

This is a standardized scale and it has been designed comprehensively to measure
the postoperative fatigue among the patients who recover from surgery (Zargar-Shoshtari,
Sammour, Kahokehr, Connolly, & Hill, 2009). The translated version (Kannada) of the
tool was utilized for this study. Language validity was established with the help of language experts by following translation and back translation method.

**Pretesting**

Pretesting was done by administering the Identity Consequences Fatigue Scale to five patients after the CABG surgery. The tool was found to be feasible and no difficulty was faced by the patients to answer the questions. The average time taken for the patients to fill this instrument was around twelve minutes.

**Reliability**

Internal consistency of this scale was calculated using Cronbach’s alpha coefficient by administering the ICFS to twenty samples. The calculated value for the scale was .90. Hence, it was considered to have adequate internal consistency and reliable to measure the comprehensive post-operative fatigue.

**Tool 7. Barnason Efficacy Expectation Scale (BEES)**

Barnason Efficacy Expectation Scale (BEES) was specially designed to measure self-efficacy among the patients undergoing CABG surgery (Barnasaon, Zimmerman, Atwood, Neiveen, & Schmaderer, 2002).

The BEES instrument (Appendix D7) comprised of 15 items regarding the self-care activities expected from the patients and self-efficacy among patients undergoing CABG surgery. The investigator got the permission from the author to use this instrument in this study (Appendix A7). The BEES was administered on 5th post-operative day and during the first and third month follow-ups in the experimental and control group to measure the self-efficacy level.
Each item was rated based on patient’s perception of confidence (Self-efficacy) in his/her ability to perform (efficacy expectation) the stated behavior using a 1- 4 point Likert scale ($4 = \textit{strongly agree}; 3 = \textit{agree}; 2 = \textit{disagree}; \text{and } 1 = \textit{strongly disagree}$). The total score of the instrument is calculated by totaling all the ratings of each question and has the score range between 15 and 60. The higher scores reveal the greater self-efficacy among the patients undergoing CABG surgery.

Validity

This is a standardized tool and it is found to be the appropriate tool for assessing the self-efficacy among patients undergoing CABG surgery (Barnason et al., 2003). The translated version (Kannada) of the tool was utilized for this study. Language validity was established with the help of language experts by following translation and back translation method.

Pretesting

Pretesting was done by administering the Barnason Efficacy Expectation Scale to five patients after the CABG surgery. The tool was found to be feasible and no difficulty was faced by the patients to answer the questions. The average time taken for the patients to fill this form was five minutes.

Reliability

Internal consistency of the scale was calculated using Cronbach’s alpha coefficient by administering the BEES to twenty samples. The calculated value for the scale was .87. Hence, it was considered to have adequate internal consistency and reliable to measure the self-efficacy skills.
Tool 8. Quality of Life Index - Cardiac Version IV

The quality of life of the participants was measured by using the Quality of Life Index - Cardiac Version IV (Appendix D8) and it was developed and validated by Ferrans and Powers (Smith, Taylor, & Mitchell, 2000). The investigator got the permission from the author to use this instrument in this study (Appendix A8). The instrument comprised of four domains (functional and health status contains 15 items; economic and social contains 8 items; spiritual and psychological 7 items; and family contains 5 items). The assessment is based on an evaluation of quality of life in individual domains and an assessment of overall quality of life.

The instrument is divided into two parts and both the part comprised of thirty five items. In the first part, the patients report their levels of satisfaction on a six-point Likert scale in individual domains of life (6 = very satisfied; 5 = moderately satisfied; 4 = slightly satisfied; 3 = slightly dissatisfied; 2 = moderately dissatisfied; and 1 = very dissatisfied). In the second part, the patients report their levels of importance on a six-point Likert scale in individual areas of life (6 = very important; 5 = moderately important; 4 = slightly important; 3 = I am not sure; 2 = unimportant and 1 = not important to me at all).

The obtained scores from part 1 and part 2 are combined to get the overall QOL scores. Possible range for the both overall QOL score and subscale is between 0 and 30. The higher scores show a better quality of life in individual domains as well as overall quality of life. The scoring procedure of Quality of Life Index (Cardiac Version – IV) is shown in (Appendix G).
This tool was administered during the first, third and sixth month of follow up of the patients in both the experimental and control group to measure the quality of life.

**Validity**

This is a standardized tool and it is found to be the most appropriate tool for evaluating the quality of life among patients undergoing CABG surgery (Penckofer, Ferrans, Fink, Barrett, & Holm, 2005). The translated version (Kannada) of the tool was utilized for this study. Language validity was established with the help of language experts by following translation and back translation method.

**Pretesting**

Pretesting was done by administering the Quality of Life Index to five patients after the CABG surgery. The tool was found to be feasible and no difficulty was faced by the patients to answer the questions. The average time taken for the patients to fill this instrument was ten minutes for each form.

**Reliability**

Internal consistency of the scale was calculated using Cronbach’s alpha coefficient by administering the quality of life index - cardiac version to twenty samples. The calculated value for the scale was .85. Hence, it was considered to have adequate internal consistency and reliable to evaluate the quality of life.
Comprehensive Nursing Intervention Programme (CNIP)

Comprehensive Nursing Intervention Programme (CNIP) was an interventional package developed by the investigator for the patients undergoing CABG surgery to improve their speedy recovery and quality of life. It had three following components:

- Pre-operative education through video
- Foot massage
- Self-care booklet - A guide to recover from CABG surgery

CNIP was validated by the experts using the criteria checklist (Appendix C5). The development, validation and administration of each component of the CNIP is described separately in the coming sections.

Preoperative Education

Preoperative education was delivered by means of video to the patients in the experimental group and the video was developed and validated by the investigator.

Development of pre-operative education video

Preparation of the first draft

The intense search of literature of published journal articles, various sources, personal experience and discussion with experienced persons in the field of cardio vascular nursing was done. The researcher met the patients who were shortlisted for CABG surgery and had a discussion to know about their perceived learning needs. Expert opinion was obtained from cardiac surgeon, cardiac anesthetist and had a discussion with the nurses working in the cardiac surgical wards to decide the components of preoperative education.
The finalized content covered in the first draft of preoperative education were

- Introduction about the heart
- Coronary artery disease
- Health history of the patients
- Diagnostic procedures done before CABG surgery
- Preoperative preparation of the patients
- Coronary artery bypass graft surgery
- Intensive care unit experiences
- Pain management
- Nutritional management
- Discharge and follow up

**Development of criteria checklist**

The criteria checklist was developed and it consisted of two point criteria; agree, disagree on relevance, accuracy, appropriateness and remarks column for suggestions

**Content validation**

First draft of preoperative education along with criteria checklist were submitted to 12 experts (both national and international) from different disciplines which included five nursing experts, four cardiovascular nursing experts one cardiac surgeon, cardiologist, and cardiac anesthesiologist (Appendix C1). All the above experts were working professionals in health care institutions / hospital in different parts of world at the level of Professors, Associate professors and Clinical Practitioners. There was 100 % conformity on the content areas of preoperative education. Content validity index was calculated and obtained CVI score of 1.
**Suggestion from the experts**

- To add component on coughing and deep breathing exercises
- To keep the content simple, clear and comprehensive
- To include some real pictures taken in the research set up
- Duration of video should not be more than 12 – 15 minutes
- Professional audio recording
- Prepare the video with help of professional video editor
- To prepare the video in both English and Kannada language

**Preparation of final draft**

The final draft was prepared by incorporating all the applicable and acceptable suggestions of the experts. The final draft of the content was translated in to Kannada language by a professional language editor. All applicable suggestions given by the experts were incorporated in preparing the preoperative educational video.

**Preparation of video**

- Script was prepared and arranged in a logical sequence in English
- Translation and retranslation of the script was done and language validity was established
- Photo shoots for the original pictures were done in the research setting and also collected all other relevant images
- Informed consent was obtained from all the persons whose pictures were taken for preparing the video (Appendix B3)
• Voice recording of the script (both English and Kannada language) was done with the help of a professional voice expert at School of Communication, Manipal University, Manipal

• Editing, sound mixing and recording were done

• Video editing was done with the help of professional video editor at audio-visual department of Manipal University, Manipal

• Duration of video was 12 minutes.

**Validation of video**

• Both English and Kannada videos were submitted to the five nursing experts for the purpose of validity

• Video was also shown to cardiac surgeons, cardiac anesthesiologist and cardiac nurses working in the intensive care unit and obtained their suggestions

• Evaluation was done on the basis of criteria checklist (Appendix C6)

• Video was also shown to five patients who were shortlisted for CABG surgery

All the experts and patients agreed on the content, language, organization and style of presentation. A few suggestions given by them were

• Improve the visibility and quality of the text in the video

• To add pictures of self-care booklet in the video

• To keep the duration of video between 10 and 12 minutes

All applicable and acceptable suggestions were incorporated and the final video on preoperative education was prepared.
Foot Massage

Massage is the manipulation of superficial, connective tissue and deeper layers of muscle using different methods, to diminish muscle reflex activity, improve function, benefit in the healing process, inhibit motor-neuron excitability and improve relaxation and well-being (Martorella, Boitor, Michaud, & Gelinas, 2014).

Foot massage focuses on the foot, massage of the sole and dorsum of the foot is often performed purely for relaxation after the surgery. In this study foot massage is administered for a duration of ten minutes in each foot with total duration of twenty minutes per day in both the legs between 2nd and 5th post-operative days.

Procedure

The procedure has following steps in performing foot massage (Appendix E1)

Step 1. Perform lubrication of the foot along with sole with mild oil, start lubricating from sole of the foot

Step 2. Give friction to soles with the help of palm by grasping the legs with one hand at ankle

Step 3. Perform knuckle stretching with right hand over the sole. Move the knuckles in small circle and press hard over the entire sole including the lateral part

Step 4. Press the sole on the reflex areas with tips of the thumbs of both hands over the entire sole
Step 5. Give friction to dorsum of the foot and the side of the foot and vigorously from toe to heel

Step 6. Do thumb kneading near the heal with the tips of fingers several times

Step 7. Squeeze the foot inward, grasp the foot between the heal of hands and pressing the middle of sole, repeat it several times

**Researcher Training**

Researcher completed one month training in foot massage at Pranava Yoga and Naturopathy Centre, Mangalore from June 27, 2014 to July 26, 2014. Training program consisted of theory classes about various concepts of massage therapies and foot massage, practical sessions, and demonstration of foot massage. Researcher got certified in foot massage after completion of the training (Appendix E2).

**Self-Care Booklet (SCB)**

Self-care activities following heart surgery are very important for the patients having speedy and healthy recovery. In this study self-care booklet (SCB) - A guide to recover from CABG surgery refers to informational booklet prepared on various aspects of self-care activities after the CABG surgery based on the perceived learning needs of the patients.

The intense search of literature of published original research articles, personal experience and had discussion with cardiac surgeons, nurses working at postoperative cardiac wards to know about the common questions raised by the patients on self-care and follow up activities during their discharge from the hospital. The researcher met the
patients who underwent CABG surgery and waiting for discharge and interviewed to know about their perceived learning needs on self-care activities.

The following areas of the content were identified and prepared in the first draft of self-care booklet:

- Introduction
- Care of incision site
- Infection control
- Medications
- Side effects of medication
- General tips on consuming medications
- Activity
- Exercises
- Dietary pattern
- Psycho social wellbeing

**Content validation**

The first draft of self-care booklet was given to 12 experts (both national and international) from different disciplines for the purpose of content validation along with criteria checklist, which included five nursing experts, four cardiovascular nursing experts, one cardiac surgeon, cardiologist, and cardiac anesthesiologist (Appendix C1). All the above experts are working professionals in health care institutions/hospital in different parts of world at the level of Professors, Associate Professors and Clinical Practitioners. There was 100 percent conformity on the content areas of preoperative education. Content validity index was calculated and obtained CVI score of 1.
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**Suggestion from the experts**

- To keep the content simple, clear and easy to understand
- To add relevant pictures in the each component
- To mention each step of foot massage with appropriate pictures

**Preparation of final booklet**

The final self-care booklet was prepared by incorporating all the applicable and acceptable suggestions given by the experts. The final draft of the content was translated into Kannada language and retranslated by language experts to ensure the language validity. The booklet was prepared in both English and Kannada.

**Ethical Considerations**

**Administrative Permission**

Administrative permission was obtained from the Dean, Manipal College of Nursing (Appendix A3), Head of the Department of Cardiovascular & thoracic surgery (Appendix A4) and Medical Superintendent of Kasturba hospital, Manipal (Appendix A3). PhD Committee, Manipal University, Manipal approved the trial on 3rd April 2014.

**Ethical Clearance**

The study was approved by Institutional Research Committee (IRC), Manipal College of Nursing, Manipal in December 2013 (Appendix A1). Institutional Ethics Committee (IEC) of Kasturba Hospital, Manipal approved the study on January 14, 2014 (IEC52/2014) (Appendix A2).
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Trial Registration

The present study was registered in Clinical Trial Registry of India (CTRI) on September 10, 2015. Trial registration number is: CTRI/2015/09/006173 (Appendix-A9).

Informed consent

A detailed subject information sheet was given in Kannada to all the participants before enrolment to the study (Appendix B1). Complete details about the research study, their involvement, benefits and harm (none) as well as whom to contact incase if they had doubt participation were clearly explained to each participant (Appendix B2). The researcher obtained individual written consent from the participants before including them in the trial. The written informed consent for taking pictures was obtained from all the patients, whose pictures were taken and utilized for the purpose of making video on preoperative education (Appendix B3).

Pilot Study

A pilot study was conducted in Kasturba Hospital Manipal from December 2014 to July 2015. The specific aim of the pilot study was to assess the feasibility of the design and to test the feasibility of comprehensive nursing intervention programme. The patients included had the same characteristics as the study population. Informed consent was taken and were randomly allocated five each to experimental and control group. The baseline assessment was taken from the sample before the intervention. Preoperative education was done one to one basis and foot massage was administered between 2\textsuperscript{nd} and 5\textsuperscript{th} post-operative period. Self-care booklet was given to the patients before the discharge. No intervention was applied to the control group and only assessments were done. The
patients follow up were at outpatient department during the first, third and sixth month. Hence, the study design and comprehensive nursing intervention programme was found to be feasible no change was made in the plan of intervention and assessment part of the study.

Data Collection Procedure

The randomized controlled trial was conducted from August 2015 to January 2017 in Kasturba hospital, Manipal. Administrative permission was obtained from the concerned authorities. The participants were selected based on the inclusion and exclusion criteria. Adequate information was provided and written consent was taken from the study participants. The study participants were also informed about the study and they were assured of the confidentiality of the information given. The participants who agreed to take part in the study were given sequentially numbered, sealed, opaque envelopes. Based on the number read out by them, they were randomly allocated into experimental and control group.

The researcher collected the socio-demographic and clinical variables. Kannada translated STAI was administered to measure the trait and preoperative state anxiety among the selected participants for the study. Preoperative education video was shown a day before the CABG surgery to all the participants in the experimental group on one to one basis, followed by discussion with them. They were also given chance to clarify their doubts or concern if they had. The preoperative education was given in a separate room in calm environment. The control group did not receive the preoperative education, however they received routine care of the hospital.
On second postoperative day the intensity of pain, fatigue, state anxiety and bio
physiological parameters were assessed for the participants both in the experimental and
control group. Foot massage was administered to all the participants in the experimental
group for a duration of 20 minutes in both the feet for four consecutive postoperative days
from day 2 to 5. Foot massage was not given to the participants in the control group. On
fifth postoperative day after the intervention the intensity of pain, fatigue, state anxiety and
bio physiological parameters were measured in both the experimental and control group.

Before the discharge from the hospital on 5th postoperative day self-efficacy was
measured for the participants in both the experimental and control group. Self-Care
Booklet - a guide to recover from CABG surgery was given to all the participants in the
experimental group, advised them to read and follow the instructions given in the booklet
after the discharge from the hospital. Foot massage was demonstrated to the patients and
their relatives before the discharge and advised them to follow it in the home with the help
of booklet given to them. To ensure the follow up of foot massage at home a daily log
(Appendix-H) was given to the patients and also they were reinforced during the follow up.
Control group did not receive the intervention of self-care booklet.
Table 3

Data Collection Plan

<table>
<thead>
<tr>
<th>Group</th>
<th>Baseline Pre-operative (STAI, SDV, CV)</th>
<th>CNIP Pre-operative education (video)</th>
<th>2\textsuperscript{rd} Post-op day</th>
<th>B: Foot Massage (Day 2-5)</th>
<th>C: Self Care Booklet</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental Group</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>SAI, VAS, FVN, BPP</td>
<td>SAI, ICFS, BEES, QLI</td>
</tr>
<tr>
<td>Control Group</td>
<td>✓</td>
<td>×</td>
<td>×</td>
<td>×</td>
<td>SAI, VAS, FVN, BPP</td>
<td>SAI, ICFS, BEES, QLI</td>
</tr>
</tbody>
</table>

Note: STAI = State Trait Anxiety Inventory; SDV = Socio-Demographic Variables; CV = Clinical Variables; SAI = State Anxiety Inventory; VAS = Visual Analogue Scale; FVN = Fatigue Visual Numeric; BPP = Bio-Physiological Parameters; BEES = Barnason Efficacy Expectation Scale; ICFS = Identity Consequences Fatigue Scale; QLI = Quality of Life Index;

During their follow up visits in the outpatient department of Cardiovascular and Thoracic Surgery, state anxiety, self-efficacy, fatigue and quality of life were measured among the study participants in both the experimental and control group. State anxiety was measured during the first month follow up. During their third month follow up self-efficacy, fatigue and quality of life was measured and during the 6\textsuperscript{th} month follow-up only quality of life was measured. Compliance to foot massage was ensured during the follow up. Complete plan of data collection is shown in Table 3.
Plan for Data Analysis

SPSS (Statistical Package for the Social Sciences) would be used for analysis of data. With the consultation of a biostatistician plan for data analysis was prepared. Based on the objectives of the study and hypothesis to be tested it was planned to use descriptive and inferential statistics. Descriptive statistics such as frequency, percentage, mean and standard deviation would be used. Chi-square test will be carried out to test the homogeneity of all baseline outcome measures among the patients in the experimental and control group. Fisher exact value will be considered if the frequency cells were lesser than five. Repeated measures ANOVA, and ‘t’ test would be applied to test the effectiveness of the Comprehensive Nursing Intervention Programme.

In repeated measures ANOVA to check for the assumption of sphericity violation Machly’s test was will be used. In case of violation of sphericity, Greenhouse Geisser correction will be used (p<.05). In order to explore the difference in outcome variables at different time points of measurements, post-hoc test using bonferroni correction will be computed and pair wise comparison of the experimental and control group will be done. Lost to follow-up data associated with the intention to treat (ITT) analysis would be replaced with the last recorded value (LOCF - last observation carry forward).
Summary

This chapter described the approach of present study and research setting, design of the study, population, sample, randomization procedure and sampling criteria. The study adopted a quantitative approach with a randomized controlled trial design. Subjects were allocated into experimental and control groups using block randomization. The chapter also gives the description of data collection tools, development and validation of Comprehensive Nursing Intervention Programme (CNIP), pilot study, data collection procedure and data analysis.