CHAPTER - III
RESEARCH METHODOLOGY

This chapter depicts the approach to be used to gather and analyze the information to achieve the study objectives. It has vital implications for the validity and reliability of the study result. The methodologies of research point out the universal blueprint for systematize the process of gathering suitable and consistent data for a search. 3rd Chapter deals with methodology of the study. The contents incorporated in this chapter are Research Approach, Research Design, Variables under study, study setting, population, samples and sampling method, Development and details of tools, Data collection procedure, details about interventions, Pilot Study details & data testing method of the study conducted.

RESEARCH APPROACH

Choosing research approach comprises one of major judgments, as the approach chosen for research project can seriously have an effect on its result. It is the basic process for gathering data in a research circumstances. The research approach is a methodical, objective means of innovation with experiential proof and meticulous control. The research approach indicates the basic plan that the investigator takes on to develop matters that is correct & interpretable. The control is accomplished by embracing circumstances steady and changing only the observable fact in the study. To achieve the objectives of the present study the investigator had selected Quantitative research approach as an appropriate one. Quantitative research is the research based on conventional scientific means, which produce numerical data and frequently seeks to found causal associations between 2 or more variables, using numerical methods to examine the potency and significance of the relationships.

RESEARCH DESIGN

Research design means plan that the Investigator selects to develop information which is correct, rationale and important for study. Choosing a study design is the most important step to give an outline for the study. The research design includes some of the significant procedural judgment that the Investigator makes to carry out the study. It helps out the Investigator in selecting the samples, interventions and observations to be done and the statistical testing to be adopted to figure out the data. Selection of research design is based on the purpose of the research, variables to be influenced and the circumstances under which the trial may be conducted, as stated by Best, W. (1992). Quasi experimental non
equivalent pre test post test control group design was selected for the study. Keeping the hypothesis and objectives in mind this design was selected for the present study. In the experimental study design, the researcher studies the cause and effect relation by exposing the investigational group to the intervention.

The design adopted can be represented as:

<table>
<thead>
<tr>
<th>Group</th>
<th>Pre Test</th>
<th>Treatment</th>
<th>Post Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental</td>
<td>0</td>
<td>X</td>
<td>O₁, O₂, O₃, O₄, O₅,</td>
</tr>
<tr>
<td>Control</td>
<td>0</td>
<td>----</td>
<td>O₁, O₂, O₃, O₄, O₅,</td>
</tr>
</tbody>
</table>

**Figure 2: Symbolic Representation of the Research Design**

The interpretation of the symbols is as follows:

O : Pre-test to the Experimental and Control group

X : Administration of Sensory Stimulation programme to the Experimental group only.

---- : No treatment.

O₁ to O₅ : Post-test to the experimental and control group.
Figure 3: Schematic diagram of the Research Design.
VARIABLES UNDER STUDY

In data analysis the Investigator gets the differentiation among the primary data and data at the end of the experiment which depicts the influence of the independent variable on dependent variable. A variable in research is phenomena that vary.

**Independent variable:** Independent variable is the state or attribute that the investigator influences or controls in an effort to determine their connection to experiential phenomena. In this study, the independent variable was a **Sensory Stimulation Programme**.

**Dependent variable:** The dependent variables are the circumstances or characteristics that emerge, vanish or modify as the researcher apply, remove or alter the independent variable. In this study, the dependent variables were the neurological status of the patients with a stroke which was assessed by using Hemispheric Stroke Scale and Barthel Index Scale.

RESEARCH SETTING

Research setting means the place where the research was conducted in order to collect the data. In this study data was collected in Bharati Hospital Pune, Krishna Hospital, Paud road Pune, Rao Nursing Home Satara road Pune, Shashwat Nursing Home Kothrud Pune. Samples were selected from various units of these hospitals like ICU, HDU, male medicine wards, female medicine wards, and private rooms. The rationale behind doing the study in the selected hospital was:

- Thorough understanding with the setting.
- Accessibility of the subjects.
- Practicability of conducting the study.
- Easy access to researcher.
- Managerial support and anticipation of co-operation for the study from various employees.

POPULATION

**Population** refers to the people in which the Investigator is concerned and to which she would desire to create a comprehensive statement of the study results. The term target population refers to any definable cluster of individuals who are experiencing a difficulty or need. In this study target population were the patients with stroke.

**The accessible population** refers to the aggregate of cases that authenticate the selected norms and that are reachable as samples of the research. The accessible population for the current study was the patients admitted with stroke in selected study settings. The population was easily accessible to the Investigator as she was posted as a clinical supervisor for
undergraduate and postgraduate nursing students in Bharati Hospital and Research Centre Pune. Rao Nursing Home, Satara Road Pune, Krishna Hospital, Paud road Pune and Shashwat Nursing Home Kothrud Pune were easily accessible to researchers.

**SAMPLE**

A sample is a part of the population being considered for study. It stands for the bigger population and is used to have conclusions about that population. In this study the sample was the patients admitted with stroke and fulfill the inclusion criteria decided by the researcher i.e. Had stable vital signs at least for last 24 hours, Patients with ischemic and hemorrhagic stroke, a MMSE score between 10-25 i.e. mild to moderate degree of impairment, and GCS score of 9-15.

**SAMPLE SIZE**

Sample size is the number of subject elements from which information is gathered in order to identify that findings are statistically significant or not. The sample size depends on many factors which may include the indicators selected, the baseline standards of the indicators in the research population and the extent of change one desires to be able to determine correctly.

The estimated sample rate for an observational study is decided by the following aspects:

- The approximate occurrence of the variable of importance in this study – that was the stroke patients.
- The expected level of confidence.
- The absolute accuracy (adequate margin of error)

The number of samples was decided using the formula:

\[
N = \frac{Z^2 [P(1-P)]}{d^2}
\]

N = sample size required for study  
P = estimated patient’s rates with stroke  
Z = 1.96 (table value at 0.05 level of significance)  
D = absolute precision (acceptable margin of error) was  

Assumed to be 5% (0.05)

So,

\[
N = \frac{1.96^2 [0.14 \times (1-0.14)]}{0.0025}
\]
3.8416 x [0.14X0.86]  
= --------------------------  
0.05

3.8416 X 0.1204  
= ------------------------  
0.0025

0.46252864  
= --------------------------  
0.0025

N = 185

So required sample size for the present study as per calculation was 185.

But taking into consideration the days of intervention (28 days) and time period of sample assessment (84 days) during second PhD presentation it was suggested by the experts to decrease the sample size to 100 i.e. 50 in experimental and 50 samples in control group.

**SAMPLING TECHNIQUE**

Sampling technique means method of selecting division of the population to obtain details of a observable facts in a way that it correspond to the whole population. Option of sampling technique depends on selected problem for study, variables comprised in the study, the form of study approach, research design and sample size. In the present study, a ‘non-probability purposive sampling’ was chosen for selection of sample.

**SAMPLING CRITERIA**

Patients were selected based on following criteria:

**Inclusion criteria:**

The present study included the patients:

- With ischemic and hemorrhagic stroke.
- Who had stable vital signs at least for last 24 hours.
- With MMSE score between 10-25 i.e. mild to moderate degree of impairment
- With GCS score 9-15

**Exclusion Criteria**

The present study excluded the patients:

- Who are with psychological and cognitive disorder
- Who had chronic and secondary stroke
Who had history of blindness, cerebral assault or any other pathological conditions related to brain, seizures, hearing loss, and h/o any neurological deficit

Had Cardiac arrest.

Who are with Transient Ischemic Attack.

Had undergone craniotomy for stroke.

Had History of neuropathy, Peripheral Vascular Disease, Alzheimer, leprosy

**Tool & Technique of Data Collection**

The phenomena in which a researcher is interested must eventually be translated into data that can be calculated. High quality info can be collected by interviewing and observation. Majority of nursing investigations involves self-report. A tool is an instrument used to gather the actual information desired by the investigator. It is developed scientifically to record the precise quantity of the observable fact under study.

A valid & reliable data collection tool is considered important to yield high-quality data. A survey of both research and non-research literature on the “effect of sensory stimulation program on neurological status of patients with stroke” was done to decide upon the tools to be selected and developed for the present investigation undertaken by the researcher. Based on the objectives of the research subsequent data collection tools were selected and prepared to obtain necessary data.

- Hemispheric Stroke Scale
- Barthel Index Scale
The summary of the data collection tools and techniques is depicted below in Table 1.

**TABLE 1**

<table>
<thead>
<tr>
<th>Tool</th>
<th>Section of the tool</th>
<th>Purpose</th>
<th>Data collection technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information sheet to collect the information.</td>
<td>Section-I- A socio-demographic data</td>
<td>To collect background data</td>
<td>Interview technique</td>
</tr>
<tr>
<td></td>
<td>Section-I- B clinical characteristics.</td>
<td>To collect clinical data</td>
<td>Record analysis and interview technique</td>
</tr>
<tr>
<td>Standard tool to assess neurological status</td>
<td>Section-II Hemispheric stroke scale</td>
<td>To assess the neurological status</td>
<td>Physical assessment and examination</td>
</tr>
<tr>
<td></td>
<td>Section-III Barthel Index scale</td>
<td>To assess the dependence status which indirectly shows neurological status</td>
<td>Observation</td>
</tr>
</tbody>
</table>

Development of a tool to collect the demographic and clinical data:

A Performa was prepared for collecting demographic data and clinical data. For the choice of the items and to prepare the tools the following steps were adopted:

- A critical review of literature of research studies and non-research articles done in related areas.
- The expert’s opinion was taken to make certain the significance and suitability of the items.
- An informal discussion was held with a guide, nursing experts, statisticians, and neuro physicians. This helped to identify the points to be included.
- Professional experience of the researcher in medical and surgical nursing field helped in determining the points to be included.

The tools selected to assess the neurological status i.e. Hemispheric Stroke scale and the Barthel Index scale (Stroke Center — www.strokecenter.org.) taken from net (permitted to use for non-commercial use) are standard tools. Interpretation of the score was done by the researcher with the guidance of the research guide. The standered tools were modified with the days the neurological status to be observed.

The major steps taken for the development of the Performa were:
- Define the construct to be measured.
- Item modification
Assess the tool for content validity.
Prepare instructions for respondents.
Conduct Pre-test and pilot study for feasibility of main study
Establishing validity and consistency of the tool.

Description of the tool:
It was composed of three sections:

Section I – A Comprised of 10 items on personal data – age, gender, occupation, monthly income, type of family, educational status, Habits, Food, physical activities, and exercises.

Section I – B comprised of six items on clinical data such as side affected, weight, cholesterol level, vascular risk factors, cerebral territory, and stroke type.

Section II- Hemispheric stroke scale comprised of 22 neurological assessment points under main headings of GCS, language, other cortical function, and cranial nerves, motor functions, and sensory functions. GCS contains best eye-verbal and motor responses. Under Language heading, the patients were assessed for comprehension, repetition, naming, and fluency. Other cortical functions and cranial nerves were assessed for the visual field, gaze, facial expression, dysarthria, dysphagia, neglect syndrome and visual construction. In the motor assessment, all four limbs were assessed for proximal and distal movements and for strength. Other motor assessments were deep tendon and pathological reflexes, muscle strength, and walk. The sensory section contains an assessment of Primary modalities (of affected side only), arm and stereognosis. The scoring of the hemispheric stroke scale was maximum score is being 100 which is considered as bad score and the minimum score is 0 which was considered as a good score. The hemispheric scale had five main sections i.e. GCS- score 15, speech with score 20, other cortical functions and cranial nerves with score 17, motor function with score 40 and sensory score 7.

Table 2
Interpretation of Neurological Status According to Hemispheric Stroke Scale.

<table>
<thead>
<tr>
<th>Neurological status</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bad</td>
<td>&gt;63</td>
</tr>
<tr>
<td>Satisfactory</td>
<td>43-63</td>
</tr>
<tr>
<td>Good</td>
<td>0-42</td>
</tr>
</tbody>
</table>
The tool contained the assessment of GCS, speech, cranial nerves, motor, sensory and other cortical functions. To assess language, the patients were asked to follow 3 commands. To assess comprehension, asked the samples to name 3 things, to repeat 3 words, to name the things as much as possible within a minute starting with letter ‘A’, excluding proper names which shows fluency. The score in this tool was negatively scored. So as the patient’s condition improves the score decreases.

* In this research Hemispheric Stroke Scale score above 63 was considered as Bad Neurological Status. Patients having bad neurological status were:

- Not able to follow all 3 commands (comprehension) like ‘stick out your tongue’, ‘touch right or left ear and then right of left knee with affected hand’, (using unaffected side) ‘point to the door’ or they were able to follow only one command.
- Patients were not able to name the items asked in the tool i.e. Wristwatch or belt, strap or belt buckle of wristwatch, index finger or ring finger. Patients were able to name only one or two items. When asked to repeat they were not able to repeat anything or were able to repeat only simple words like dog or cat.
- They were not able to speak at all or were not able to recognize moving finger.
- In assessment of other cortical functions and cranial nerve assessment visual field assessment may show severe loss; i.e. Inability to recognize moving hand, no response to threat.
- Patients may show moderate loss like inability to stare moving finger, deviated gaze, severe weakness and drooling, severe dysarthria, dysphagia, neglect syndrome like denial of body part (anosognasia), unable to copy any figure.
- In motor function patient may have no movement or trace of movement or may have motion without gravity in arm proximal and distal and leg proximal and distal.
- Deep tendon reflexes may be hypoactive or hyper active, babinski reflex may be abnormal, abnormal muscle tone.
- Gait assessment may show inability to stand and stand only with support. In sensory assessment the affected side may show decreased sensation.
- Patient may be unable to distinguish between two things by touching, (stereognosis). GCS score may be less than 10.

* Hemispheric Stroke Scale score in between 43-63 is considered as satisfactory Neurological Status. Patient having satisfactory neurological status were be able (language part) to:
Follow any two commands out of three, able to name any one or two things, able to repeat one or two words or a simple sentence, moderate fluency in telling words.

In assessment of other cortical functions and cranial nerve assessment moderate loss in visual field, moderate dysarthria, moderate dysphagia, mild anosagnosia, can copy some figures.

Motor assessment may show moderate weakness in arm proximal and distal and leg proximal and distal,

May or may be change in reflexes and muscle tone, moderate anaesthesia,

May be able to distinguish between key and coins.

GCS more than 13

Hemispheric Stroke Scale score in between 0-42 is considered as Good Neurological Status. Patient having good neurological status were be able to (language part) follow:

Two or all commands, able to name two or all names, able to repeat two or all words with sentence, may show improved fluency.

In assessment of other cortical functions and cranial nerve assessment, improved or normal visual field, improved gaze, facial expression may show slight asymmetry during smile or may be normal,

Moderate to normal dysarthria and dysphagia, able to bisects line in middle, can copy cross and 3d drawing cubes.

Improved motor function may show mild weakness in arm proximal and distal and leg proximal and distal. All reflexes and muscle tone may be normal.

Gait might be improved to mild abnormal to minimal abnormal.

Sensation may be improved mild hypaesthesia to normal, were able to distinguish two similar sized coins. GCS more than 13.

Section III- Barthel index scale comprises of 10 points under the main headings Feeding, Bathing, Grooming, Dressing, Bowel, Bladder, Toilet Use, Transfer from bed to chair and back, Mobility and Stairs.
Table 3
Interpretation of dependency status according to
The Barthel Index

<table>
<thead>
<tr>
<th>Interpretation</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total dependence</td>
<td>0--20</td>
</tr>
<tr>
<td>Severe dependence</td>
<td>21--40</td>
</tr>
<tr>
<td>Moderate dependence</td>
<td>41--60</td>
</tr>
<tr>
<td>Slight dependence</td>
<td>61--80</td>
</tr>
<tr>
<td>Independence</td>
<td>81--100</td>
</tr>
</tbody>
</table>

The tool contains the assessment of patient’s dependence level while doing every day actions like feeding, taking bath, cleaning, wearing cloths, passing urine and motion, using toilet and able to move from bed to chair and back to bed, & climbing stairs. Each item is scored separately. There is positive scoring in this tool. So as the patient’s condition improves score increases. Researcher has interpreted the total score in five levels - Total Dependence, Severe Dependence, Moderate Dependence, Slight Dependence, and Independence state.

* The score for total dependence is 0-20. In this level patients are unable or dependent to do above mentioned maximum activities like having food, taking bath, grooming, putting on clothes, using toilet for urination and for passing stools and moving from bed to chair and back to bed, walking, and climbing on stairs.

* The scores for severe dependence and moderate dependence is 21-40 and 41-60 respectively. In these levels also patients are unable or dependent on others for maximum activities but tries to perform some activities with help and on their own and may met with occasional accidents like fall or breaking things etc.

* The score for slight dependence is 61-80. In this level patients are independent in doing certain activities like having food, grooming, urination, some movements on flat surfaces but need assistant for toilet use, and moving from bed to chair and back to bed, mobility and climbing on stairs.

* Score for independence is 81-100. In this level patients usually become independent for activities eating, taking bath, and getting tidy up, dressing up, use of toilet for bowel and bladder movements. But still may need some help and may use aids like
sticks while walking. Even patients may have occasional accidents. They may have full control on bladder and bowel activities.

**Description of the intervention: Sensory Stimulation Programme (SSP)**

The rationale of the researcher in the present study was to apply a patient-centered intervention to improve the neurological condition of stroke patients by giving Sensory Stimulation Programme (SSP). SSP is an experimental treatment that intends to make use of mechanisms of neural plasticity to aid in the improvement of somatosensory function after brain function impairment due to traumatic brain injury, brain hemorrhage or cerebral stroke. Neuro-plasticity is the ability of the brain to restructure itself by the growth of new neural links all the way through life. It allows the nerve cells in the brain to recompense for damage and illness and to regulate their actions in reaction to new circumstances or to changes in their situation. Traumatic cerebral injury, brain hemorrhage or cerebral strokes are notorious sources of cognitive loss, either by neural death or by the deteriorating of neural links. Sensory Stimulation Programme is stimulating a patient with desired stimulation of five senses in a programmed style at a fixed interval. The SSP deals with all 5 sensory modalities, touch, taste, smell, hearing, and Visual senses. The stimulus is selected keeping in mind all age group people and is harmless to human beings but provokes the sensory organs effectively.

**Olfactory Stimulation:** The researcher applied a drop of lavender oil on the pillow and on patient’s dress using a cotton swab at morning and at evening for 28 days. The researcher also applied talcum powder with the lavender aroma on the body.

**Auditory stimulation:** Auditory stimulation was given by providing Shehanoï music with 50% volume and 50-60 decibel for 30 minutes twice daily at morning and evening. In addition to this researcher was verbalizing with patients regarding their favourite subjects.

**Visual stimulation:** Visual stimulation was given by providing Mirror Therapy to patients. Mirror therapy stimulates ocular attention and it make the eyes to captures optical signals. In mirror therapy the client’s paralysed hand was placed behind the mirror in such a way that the reflection of the other limb appears as affected limb which was placed behind the mirror box. During the movement or exercise of normal limb, clients observe its reflection in mirror which makes him to feel that his paralysed limb is moving. Observing the reflective image enhance excitability of the ipsilateral motor cortex. MT depicts the use of motor copy strategy which involves bimanual movements followed by forced use of the paralysed limb. Mirror therapy is given twice daily at morning and evening for 10 minutes for 28 days.
**Tactile Stimulation:** Retrograde massage applied to the affected limbs using coconut oil for lubrication scented with lavender oil daily for 28 days. Massage was given using effleurage and petrissage type strokes.

Steps:

1. **Effleurage:** Effleurage was given using full palmer and flat finger surface of the in a gliding manner.
2. **Petrissage:** Petrissage massage was given by placing the hand in C shape on the areas of massage and then pushed down in to the muscle, grasp it and pull it directly up off the bone. And release in a backward half circle motion. Along with massage ROM Exercise of the affected area for 28 days was given.

**Gustatory Stimulation:** Sour and cold 50% lemon juice was given for drinking twice daily for 28 days.

Considering the feasibility of the data collection the researcher was advised by the subject experts to take assistance of patient’s relatives for the administration of intervention. Accordingly the bellow protocol is prepared and got approved by the guide

Table 4

**Protocol for application of Sensory Stimulation Programme**

<table>
<thead>
<tr>
<th>Sensory Stimulation</th>
<th>1st-4 days</th>
<th>5th-7 days</th>
<th>8th – 28 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olfactory Stimulation</td>
<td>Researcher</td>
<td>Relative in the presence of researcher</td>
<td>Researcher and relative –every alternate day</td>
</tr>
<tr>
<td>Auditory Stimulation</td>
<td>Researcher</td>
<td>Relative in the presence of researcher</td>
<td>Researcher and relative –every alternate day</td>
</tr>
<tr>
<td>Visual Stimulation</td>
<td>Researcher</td>
<td>Relative in the presence of researcher</td>
<td>Researcher and relative –every alternate day</td>
</tr>
<tr>
<td>Tactile Stimulation</td>
<td>Researcher</td>
<td>Relative in the presence of researcher</td>
<td>Researcher and relative –every alternate day</td>
</tr>
<tr>
<td>Gustatory Stimulation</td>
<td>Researcher</td>
<td>Relative in the presence of researcher</td>
<td>Researcher and relative –every alternate day</td>
</tr>
</tbody>
</table>
CONTENT VALIDITY OF THE TOOLS

Content validity is the extent to which a tool has a suitable figure of objects to sufficiently cover and assess the construct plan. Mini-Mental State Examination and Glasgow Coma Scale were used to select the sample; Hemispheric Stroke Scale & Barthel Index Scale was used to assess the neurological status of samples. After doing the required modification for present setup and study, the tools were given to 25 experts in the field of Neurology, Physiotherapy, Ayurveda, and Nursing. The tool was received from 22 experts. Among the validators 02 (two) experts were neuro physicians who were teaching and practising for a long time in the field of Neurology, 01 (one) Physician from Intensive Care Unit, 01 (one) General Physician, 01(one) Neurosurgeon, 01 (one) Physiotherapist, one Ayurveda Physician, 14(Fourteen) experts were from different fields of nursing education and clinical expertise in various medical units, 01(one) Biostatistician. As all the tools are standardized tools, there were suggestions mainly for score interpretation. The interventional tool Sensory Stimulation Programme was finalized and the final tool was translated in Marathi language and was validated by Marathi language expert. The Marathi tool was retranslated into English language and validated by English language expert.

RELIABILITY OF THE TOOL

In the present study since the observers rated the participant's behaviors, establishing equivalence was assured by inter-rater reliability test. The proposed tool reported an interrater correlation coefficient of 0.98 which represents an excellent agreement. Reliability was assessed using the Inter-rater Method. Cohen’s Kappa was found to be 0.98. Thus, the tools with these sections were found to be reliable.

PILOT STUDY

Pilot study is necessary to see the feasibility of the main study. The pilot study was conducted from 15/08/2015 to 15/04/2016 in Krishna Hospital Pune after obtaining formal permission from the Medical Director, Krishna Hospital Pune. 16 patients, 8 patients in each group (control & experimental) from Krishna General Hospital Pune were selected who met the sample criteria by using nonprobability purposive sampling technique. After building a good rapport with the patient and family, the purpose of the study were explained to the relatives and patients, and confidentiality was assured. Willingness was asked and informed written consent was obtained from each participant’s relative. Data collection was done according to the research design. No difficulties were faced throughout the pilot study.
There was full cooperation from the staff and management. The result of the pilot study revealed that it is feasible to conduct the study.

**PROCEDURE FOR FINAL DATA COLLECTION**

The task of developing an appropriate method for collecting data and translating it to a measurable construct that can be calculated is called a collection of data. These methods decide the accuracy and robustness of the conclusions of the study. The settings for this study were multi-specialty hospitals situated in Pune city. All settings were having well-equipped ICU to treat stroke patients in emergency conditions. All settings are having skilled intensivists round o’clock 24 hours. Neuro physicians visit the cases daily and also during emergencies. All the nurses are full trained with either diploma or degree in nursing. 10-15 cases of hemorrhagic or ischemic stroke patients are admitted to Bharati Hospital every month. A letter for getting permission to perform the study was forwarded to the Medical Director Bharati Hospital and Research Centre Pune, Administrator Shaswat Hospital Pune, Medical Director Rao Hospital Pune. The final study started, and was conducted on 100 samples (50 in experimental and 50 in control group) from April 2016 to July 2017 in Bharati Hospital and Research Centre Pune, Rao Nursing Home Satara Road Pune, and Shashwat Nursing Home, Kothrud Pune.
Table 5
Final Data collection schedule

<table>
<thead>
<tr>
<th>S. NO</th>
<th>Month wise samples registered for the study</th>
<th>Exp</th>
<th>Control</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>April 2016</td>
<td>4</td>
<td>2</td>
<td>Bharati Hospital and Research Centre Pune</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rao Nursing Home. Pune</td>
</tr>
<tr>
<td>2</td>
<td>May 2016</td>
<td>4</td>
<td>5</td>
<td>Shashwat Nursing Home</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rao Nursing Home. Pune</td>
</tr>
<tr>
<td>3</td>
<td>June 2016</td>
<td>2</td>
<td>3</td>
<td>Bharati Hospital and Research Centre Pune</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td>Rao Nursing Home. Pune</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Shashwat Nursing Home</td>
</tr>
<tr>
<td>4</td>
<td>July 2016</td>
<td>5</td>
<td>6</td>
<td>Bharati Hospital and Research Centre Pune</td>
</tr>
<tr>
<td>3</td>
<td>August 2016</td>
<td>4</td>
<td>5</td>
<td>Rao Nursing Home. Pune</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Shashwat Nursing Home</td>
</tr>
<tr>
<td>4</td>
<td>September 2016</td>
<td>4</td>
<td>5</td>
<td>Bharati Hospital and Research Centre Pune</td>
</tr>
<tr>
<td>5</td>
<td>October 2016</td>
<td>4</td>
<td>4</td>
<td>Rao Nursing Home. Pune</td>
</tr>
<tr>
<td>6</td>
<td>November 2016</td>
<td>5</td>
<td>5</td>
<td>Bharati Hospital and Research Centre Pune</td>
</tr>
<tr>
<td></td>
<td>December 2016</td>
<td>5</td>
<td>5</td>
<td>Rao Nursing Home. Pune</td>
</tr>
<tr>
<td>8</td>
<td>Jan 2017</td>
<td>4</td>
<td>4</td>
<td>Bharati Hospital and Research Centre Pune</td>
</tr>
<tr>
<td>9</td>
<td>Feb 2017</td>
<td>5</td>
<td>4</td>
<td>Rao Nursing Home. Pune</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<td>Bharati Hospital and Research Centre Pune</td>
</tr>
<tr>
<td><strong>Total samples</strong></td>
<td><strong>50</strong></td>
<td><strong>50</strong></td>
<td><strong>100</strong></td>
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PROCEDURE FOR DATA COLLECTION (EXPERIMENTAL GROUP)

- The administrative approval was obtained from the settings selected for the study.
- Selected the samples according to inclusion criteria i.e.
  - Had stable vital signs at least for last 24 hours,
  - Patients with ischemic and hemorrhagic stroke,
  - MMSE score between 10-25 i.e. mild to moderate degree of impairment,
  - GCS score 9-15.
- Written consent was taken from patient’s relative after explaining the study details.
- Experimental group samples were selected from Bharati Hospital and Research Centre Pune.
- The neurological status was assessed on 1st day of contact by using hemispheric stroke scale and Barthel Index scale.
- Sensory Stimulation Program started daily morning and evening according to the protocol decided.
- First four days researcher herself administered all the interventions i.e.
  - Auditory stimulation by verbalization with patients while giving SSP. Moreover providing verbal communication the researcher provided shehanoï music for 30 minutes twice daily at morning and evening,
  - Visual stimulation through mirror therapy,
  - Tactile stimulation by massage,
  - Olfactory stimulation by applying a drop of lavender oil on the pillow and on dress using a cotton swab and applying talcum powder on the body with the lavender aroma at morning and at evening and
  - Gustatory stimulation by providing sour cool lemon juice 50%/ twice daily.
- After four days up to the 7th day the researcher trained one relative who was staying with the patient continuously (usually wife with male patients and daughter in-law with female patients).
- From 8th day onwards according to the pre fixed protocol every alternate day the researcher and also a trained relative administered SSP for 28 days.
- Neurological status was assessed on 7th, 21st, 42nd, 63rd, and 84th days by researcher using research tools i.e. Hemispheric stroke scale and Barthel Index scale.
PROCEDURE FOR DATA COLLECTION (CONTROL GROUP)

- The administrative approval was obtained from the settings selected for the study.
- Selected the samples according to inclusion criteria i.e.
  - Had stable vital signs at least for last 24 hours,
  - Patients with ischemic and hemorrhagic stroke,
  - MMSE score between 10-25 i.e. mild to moderate degree of impairment,
  - GCS score 9-15.
- Written consent was taken from patient’s relative after explaining the study details.
- Sample for control group were selected from Rao Nursing Home Satara Road Pune and Shashwat Nursing Home Kothrud Pune.
- The neurological status was assessed on 1st day by using hemispheric stroke scale and Barthel Index scale.
- Neurological status was assessed on 7th, 21st, 42nd, 63rd, and 84th days by researcher using research tools i.e. Hemispheric stroke scale and Barthel Index scale.
- Information regarding SSP was given to control group after data collection period of 84 days. SSP was taught to relative.

Data collection procedure was continuously going on from April 2016 to May 2017. At a time there were 3-4 patients for interventions. There was good support from the employees and management. Patient’s relatives use to take interest and were doing intervention carefully without fail. Researcher made sure that lavender oil and powder with lavender aroma was available always with the experimental group sample. The final data were tabulated, organized and analyzed as per the plan for analysis. Master data sheet was prepared.

ETHICAL CONSIDERATION

The study was scrutinized and accepted by the Ethical Committee of the institution i.e. Bharati Vidyapeeth (deemed to be) University, CON Pune. The nature and purpose of the study was described in detail to each participant’s relative being incorporated in the study. Consent was obtained on paper after giving thorough information about the study from each participant’s relative of both the group before commencement of the study. Each participant or their relative had a liberty to ask questions and they were allowed to pull out from the trial at any time. Confidentiality and privacy of the participants was ensured by coding the data, and the findings were depicted as data of a group with no individual respondent details being stated in the compilation sheet. Information acquired from the
participants was utilised only for study reason and were kept undisclosed. The list of study sample’s names were damaged on finishing point of the study.

**PLAN FOR DATA ANALYSIS**

As per the objectives & hypotheses of research project it was planned to systematize, tabularize, analyze & infer the data by using descriptive and inferential statistics. The plan for analysis was done as bellow:

- Rate of recurrence and proportion distribution of the demographic characteristics of the sample subjects.
- Rate of occurrence and proportion allocation of the clinical characteristics of the sample subjects.
- Mean, standard deviation and range of neurological status score and dependence score of both experimental and control groups based on hemispheric stroke scale and Bathel index score respectively.
- ‘t’ value to find out the importance of mean distinction among mean pre-test and mean post test neurological status score and dependence scores of patients with stroke in experimental group based on hemispheric stroke scale and Bathel index score respectively.
- ‘z’ value to find out the end result of mean distinction among mean pre-test and mean post test neurological status score and dependence scores of patients with stroke in experimental group based on hemispheric stroke scale and Bathel index score respectively.
- Fisher’s exact test to test relationship between the findings and selected demographic and clinical variables.
- A p value of less than 0.05 was considered to be significant.

**SUMMARY**

The chapter III consists of the Methodology adopted for the present research. It comprises of the research approach i.e. quantitative, the study design, dependent and independent variables of the study, study setting, study population, sample size, selection of sample, details of the sample selected, selection of tool, tool description, validity & reliability of the tools, pilot study to see the feasibility, and process for final data gathering and data analysis planning. Next chapter contains analysis and interpretation of data.